THE IMPACT OF THE FOOD QUALITY PROTECTION ACT IMPLEMENTATION ON PUBLIC HEALTH

HEARING

BEFORE THE

SUBCOMMITTEE ON DEPARTMENT OPERATIONS, OVERSIGHT, NUTRITION, AND FORESTRY

OF THE

COMMITTEE ON AGRICULTURE HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTH CONGRESS

FIRST SESSION

AUGUST 3, 1999

Serial No. 106–29

Printed for the use of the Committee on Agriculture

U.S. GOVERNMENT PRINTING OFFICE
59–359 CC WASHINGTON : 1999

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC 20402
ISBN 0-16-059452-9

COMMITTEE ON AGRICULTURE

LARRY COMBEST, Texas, *Chairman*

BILL [illegible], Nebraska,
Vice Chairman
JOHN A. BOEHNER, Ohio
THOMAS W. EWING, Illinois
BOB GOODLATTE, Virginia
RICHARD W. POMBO, California
CHARLES T. CANADY, Florida
NICK SMITH, Michigan
TERRY EVERETT, Alabama
FRANK D. LUCAS, Oklahoma
HELEN CHENOWETH, Idaho
JOHN N. HOSTETTLER, Indiana
SAXBY CHAMBLISS, Georgia
RAY LAHOOD, Illinois
JERRY MORAN, Kansas
BOB SCHAFFER, Colorado
JOHN R. THUNE, South Dakota
WILLIAM L. JENKINS, Tennessee
JOHN COOKSEY, Louisiana
KEN CALVERT, California
GIL GUTKNECHT, Minnesota
BOB RILEY, Alabama
GREG WALDEN, Oregon
MICHAEL K. SIMPSON, Idaho
DOUG OSE, California
ROBIN HAYES, North Carolina
ERNIE FLETCHER, Kentucky

CHARLES W. STENHOLM, Texas,
Ranking Minority Member
GEORGE E. BROWN, JR., California [1]
GARY A. CONDIT, California
COLLIN C. PETERSON, Minnesota
CALVIN M. DOOLEY, California
EVA M. CLAYTON, North Carolina
DAVID MINGE, Minnesota
EARL F. HILLIARD, Alabama
EARL POMEROY, North Dakota
TIM HOLDEN, Pennsylvania
SANFORD D. BISHOP, JR., Georgia
BENNIE G. THOMPSON, Mississippi
JOHN ELIAS BALDACCI, Maine
MARION BERRY, Arkansas
VIRGIL H. GOODE, JR., Virginia
MIKE McINTYRE, North Carolina
DEBBIE STABENOW, Michigan
BOB ETHERIDGE, North Carolina
CHRISTOPHER JOHN, Louisiana
LEONARD L. BOSWELL, Iowa
DAVID D. PHELPS, Illinois
KEN LUCAS, Kentucky
MIKE THOMPSON, California
BARON P. HILL, Indiana

PROFESSIONAL STAFF

WILLIAM E. O'CONNER, JR., *Staff Director*
LANCE KOTSCHWAR, *Chief Counsel*
STEPHEN HATERIUS, *Minority Staff Director*
KEITH WILLIAMS, *Communications Director*

SUBCOMMITTEE ON DEPARTMENT OPERATIONS, OVERSIGHT, NUTRITION, AND FORESTRY

BOB GOODLATTE, Virginia, *Chairman*

THOMAS W. EWING, Illinois,
Vice Chairman
RICHARD W. POMBO, California
CHARLES T. CANADY, Florida
JOHN N. HOSTETTLER, Indiana
SAXBY CHAMBLISS, Georgia
RAY LAHOOD, Illinois
JERRY MORAN, Kansas
JOHN COOKSEY, Louisiana
GREG WALDEN, Oregon

EVA M. CLAYTON, North Carolina,
Ranking Minority Member
MARION BERRY, Arkansas
BENNIE G. THOMPSON, Mississippi
VIRGIL H. GOODE, JR., Virginia
DAVID D. PHELPS, Illinois
BARON P. HILL, Indiana
MIKE THOMPSON, California
GEORGE E. BROWN, JR. California [1]
DAVID MINGE, Minnesota

---

[1] Deceased July 16, 1999.

CONTENTS

THE IMPACT OF THE FOOD QUALITY PROTECTION ACT IMPLEMENTATION ON PUBLIC HEALTH

TUESDAY, AUGUST 3, 1999

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON DEPARTMENT OPERATIONS,
OVERSIGHT, NUTRITION, AND FORESTRY,
COMMITTEE ON AGRICULTURE,
Washington, DC.

The subcommittee met, pursuant to call, at 2:00 p.m., in room 1300, Longworth House Office Building, Hon. Bob Goodlatte (chairman of the subcommittee) presiding.

Present: Representatives Ewing, Pombo, Canady, Hostettler, LaHood, Walden, Clayton, Berry, Goode, Phelps, Hill, and Stenholm [ex officio].

Staff present: Kevin Kramp, staff director, Subcommittee on Department Operations, Oversight, Nutrition, and Forestry; John Goldberg, professional staff; Callista Bisek, scheduler/clerk; Brad Shurdut, fellow; and Danelle Farmer, minority consultant.

OPENING STATEMENT OF HON. BOB GOODLATTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF VIRGINIA

Mr. GOODLATTE. This hearing is a third in the series of oversight hearings to review the USDA's and EPA's implementation of the Food Quality Protection Act.

Today we review the affects of the administration's decisions on public health. Some may wonder why we are focusing on this issue after yesterday's high profile and political announcement. While I am sure there will be some discussion concerning Ms. Browner's remarks today, I don't think there is a better time to demonstrate how all tolerance decisions on pesticide uses are dependent on each other. The decisions made on agriculture or food uses necessarily affect the public health uses of that same chemical.

All elements and uses of pesticides are now invariably linked under FQPA. Thus, abuse of one part of the process now translates into an overall abuse of your regulatory authority under FQPA. In other words, lack of attention to any component of the process will ultimately impact and endanger other use patterns, including the agricultural uses. Remember, we are now dealing with a single risk cup relating to total exposures allowable under the Food Quality Protection Act. Abuse of process, reluctance to incorporate sound science into the process, blatant disregard for a process which envelops all the stakeholders' interests and hasty implementation po-

tentially affects all of us, both those needing pesticides to fight disease carrying insects as well as the farmers relying on a myriad of diverse pesticides for crop production. Many of the same pesticides are used for both public health control programs as well as agriculture.

It may seem that this hearing is unrelated to those previously held by this committee, but one thing remains constant—the EPA still continues to ignore the process set out for them by Congress by making decisions driven by politics rather than sound science. This is evident and painfully obvious in the outrageous decisions made yesterday for two very important agricultural pesticides.

Because time is a concern this afternoon I will keep my remarks short. I am sure many of my concerns about the process, or lack thereof, will be fully discussed during this hearing. Let me crystallize my frustration with the committee by sharing that we tried to invite the Department of Health and Human Services to testify. FQPA, after all, requires that EPA consult with the Department of Health and Human Services to ascertain benefits and use information about a public health pesticide. While they had interest and availability, unfortunately, HHS had no one at the Department level that could speak to this issue or had even heard about their statutory role in this matter.

As a last point, we all know the significance of today's date, August 3, 1999. This represents the statutory deadline for the EPA to evaluate the first one-third of all the pesticide tolerances. This deadline will likely be met. Hasty decisions to act upon azinphos methyl and methyl parathion, two pesticides used on a wide variety of fruits and vegetables without finalized science policies seem to be largely guided by political desires. Concern has surfaced that these public and highly visible decisions could have a dramatic effect on consumer confidence since much of this year's crop has already been treated and harvested. You tell me what I should say when I hand my child an apple as a nutritious snack? With no imminent hazard present which you fully acknowledge, a decision to announce such dramatic restrictions for two widely used pesticides seems unwarranted and an abhorrent abuse of power. Similar disregard for the process will limit or endanger the continuous availability of public health use pesticides.

I would now like to recognize the ranking member of the subcommittee, the gentle woman from North Carolina, Mrs. Clayton. Welcome.

OPENING STATEMENT OF HON. EVA M. CLAYTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NORTH CAROLINA

Mrs. CLAYTON. Thank you. I ask if I may revise and extend and add to my remarks. Mr. Chairman, I thank you for this hearing, and I think this hearing is necessary to try to get us back on track to see if we can implement the full intent of this bill, and try to do it with the collaboration with both Departments of Agriculture and EPA.

I take the position that the bill is needed both for Agriculture as well as for the safety of our food. I don't think it is either one or the other.

As one member of the Agriculture Committee, I happen to be very environmentally sensitive. I think it is one of my moral fibers that the creation is part of what I want to protect. I also make the assumption that farmers are the original environmentalists. Now, obviously, some care more about it than others, but I just don't assume that agriculture is out to do great harm, nor do I assume that environmentalists don't care about agriculture. So, I think there is a way where we can find the intent of this bill and to make sure that we don't have a rush to judgment, but allow that process to go as is required by law.

Also, the safety and nutrition and availability and affordability of food are essential, and I think we will hear, at least in testimony of Representative Towns as I review that, and those who will be testifying, we invite you to share with us how we can make this legislation work. We are not out to pit one group of individuals who care about the environment and another group of people who care about producing food against each other. So I hope the intent of this hearing is to see how we can get this bill back on track. Thank you.

Mr. GOODLATTE. I thank the gentle woman. The gentlemen from California, Mr. Pombo, author of the legislation.

OPENING STATEMENT OF HON. RICHARD W. POMBO, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. POMBO. Thank you, Mr. Chairman. I thank you for calling this hearing today, and given yesterday's events I feel that this hearing is certainly timely.

Just like everyone else in America, farmers throughout the Nation want a safe food and clean water. I can hardly imagine them sending food to our cities that they would not eat themselves.

American farmers take pride in growing the world's safest, cheapest, and most abundant food supply. They take pride in making sure that all of the shelves in the supermarket are filled with a clean and healthy product.

To grow these crops, family farmers depend on crop protection tools to control pests such as the coddling moth and oriental fruit moth, which can destroy the fruits, nuts and vegetables making them inedible or unmarketable. To say the least, it is an ongoing struggle to keep these pests out of the crops. Farmers use these crop protection tools within a whole management system to control pests and to provide a safe and healthy food supply.

Integrated pest management is the idea of using biological controls and reducing the use of chemical crop protection tools. However, if certain tools are completely eliminated from the IPM program, pest outbreaks could occur without a way to control them, which could devastate our food supply.

The issues of food supply go much further than the family farmers who grow the food. It reaches the inner cities. As you will hear from Mr. Towns, improper implementation of the Food Quality Protection Act will increase food costs, impacting low-income children and families the most.

Improper implementation of FQPA could cause the proliferation of cockroaches in inner-cities, thus increasing asthma for inner-city

children. It also has the potential to result in the inability to control vector insects, such as mosquitos and ticks, that pass on encephalitis and Lyme Disease to our children.

Now, I voted in favor of the Food Quality Protection Act. Today I continue to support re-evaluating the crop protection tools that our farmers use and the compounds we use to battle residential pests, but the evaluation process must be fair and accurate. It cannot be based on false science and political pressures from fringe extremist groups.

If the risk hazard for a product is too high, I would say take it off of the market. But the decision to reach that conclusion must follow rigorous scientific procedures that are agreed upon by scientists, consumers, farmers, chemical companies, and environmentalists. Solid intensive procedures are the core basis for credibility in this highly charged issue. Any organization that calls scientific procedures a "delay" tactic is a political activist group focused more on their self-recognition than in the best interest of all Americans.

My intent is to work in a bipartisan fashion to bring about a fair process in the evaluation of pest tools we must follow a rigorous and scientific process, or else the process itself will lack credibility.

All data must be considered, and outline procedures must be in place and followed rigorously. These strict procedures will allow for scientific, not political, conclusions.

When Congress passed the Food Quality Protection Act, Congress expected and intended that sound scientific principles would be used in its implementation. In fact, this is what Vice President Al Gore stated in a memorandum sent to both the Department of Ag and EPA on April 8, 1998. This memorandum laid out the White House's plan for putting FQPA's implementation on the right track. The White House's plan for FQPA implementation contained four basic principles: sound science in protecting public health, regulatory transparency, reasonable transition for agriculture, and consultation with the public and other agencies.

America's agricultural and urban pest control communities supported the Vice President's approach. Today I ask Vice President Al Gore to step up to the plate and follow through on his call for those procedures.

FQPA's implementation process is not only derailed, but terribly askew. Quite frankly, EPA's decision to act without finalized science policies is apparently political and designed to appease the fringe environmental extremists. Decisions to restrict uses prior to the completion of the critical scientific policies that are the basic framework for the EPA to base decisions upon proves this point.

Not all scientific studies have been completed and more studies are in progress. The data call in authority has been blatantly ignored and abused. Most troubling, important grower constituents have not been included in the process. At least two recent meetings were held in the Midwest by EPA, USDA, and the environmental community that did not include representatives from the affected grower community.

Why did the EPA form another group when they already have TRAC? I am convinced it was due to the fact that the environmental extremists did not like the direction that TRAC was going.

They did not like the idea that the science was showing that crop protection tools were safe for children, your children and my children.

Many of these same groups are currently accusing me of intentionally wanting to harm this Nation's children. Anyone who works with me knows that this is a malicious allegation without merit that has been put forward to distract for my bipartisan and widely supported FQPA legislation.

I have three young children of my own. I want them to have the safe and nutritious diet that I was provided as a child. Being able to eat fresh pears, apples, grapes and cherries is the best thing for our children, however, the environmental extremists, along with EPA, are trying to deny my children that nutritious diet by using incomplete science and scare tactics.

It is shameful that our own government and the environmental elite are encouraging the importation of fresh fruits and vegetables from foreign countries by claiming that our family farmers are not producing a safe product, yet our family farmers are both on the cutting edge of technology and are diligently working on reducing the use of pesticides.

I would much rather feed my children produce because I know it is safe. I know it is produced by farmers who want to produce a safe, clean product, and I know it is grown with the utmost care.

Carol Browner has stated, and I quote, "Our Nation enjoys the safest, most abundant food supply in the world." She emphasized that for children and adults alike, the benefits of a diet that includes fruit and vegetables far outweigh the risks of pesticides.

Now, without a dire emergency, why is the EPA making decisions without all of the facts and procedures in place? Carol Browner needs to stop politicizing this process by not following a rigid implementation procedure. I ask her to use sound science, all available data, and follow outlined scientific policies that will ensure our children will continue to have a safe, wholesome and abundant food supply. And I thank the chairman for the time.

Mr. GOODLATTE. I thank the gentleman. Does the gentleman from Texas have an opening statement?

Mr. STENHOLM. No.

Mr. GOODLATTE. Thank you. At this time, we are very pleased to welcome our first panelist, the Honorable Edolphus Towns, Congressman from the 10th district of New York. Congressman Towns, we very much appreciate your work in this area. Your written testimony will be made a part of the record, and we are pleased to hear what you have to say. Welcome.

STATEMENT OF HON. EDOLPHUS TOWNS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW YORK

Mr. TOWNS. Thank you very much, Mr. Chairman, and let me also thank the ranking member, Mrs. Clayton, and all the other members of this committee. I think this is a very important hearing, and I thank you for the invitation.

The Agriculture and Commerce Committees worked together to develop the Food Quality Protection Act. The act was passed unanimously by both the House and the Senate, and it was signed into law by President Clinton on August 3, 1996.

As Congress developed the legislation, I worked hard to assure that using modern technology the Nation's food supply would be as safe as possible. I also believe that it was our intent, in passing the Food Quality Protection Act, to ensure that American consumers would continue to enjoy tremendous nutritional benefits from an affordable and abundant food supply. I encourage this committee to keep these goals in mind—safety, affordability, and abundance—as you exercise oversight on EPA's implementation of the Food Quality Protection Act.

It is these three issues that have a Member from an urban area—and to be specific, Brooklyn, NY—with no agricultural production, appearing before you today. Our food must be safe, and the Food Quality Protection Act should be implemented in a manner that avoids the increase in food prices.

Food price increases would threaten consumer nutrition and increase the costs of operating USDA's important adult and child nutrition programs. As this committee well knows, these programs are often the only source of fresh fruit and vegetables which provide a nutritious breakfast and lunch for many low-income Americans.

In addition to maintaining an affordable food supply, we must also be concerned about the public health benefits of the Nation's pesticides. Public health pesticides are used to control many insects, rodents and other organisms that transmit human disease and producing human discomfort or injury, such as mosquitoes, flies, fleas, cockroaches, ticks, mites and rats. All of these public health threats are of concern to me, but I am most concerned about cockroaches.

A recent study sponsored by the National Institute of Allergy and Infectious Diseases confirms that cockroach residues increase the incidence of asthma among inner-city children, resulting in a greater absence from school, increased hospitalization, which leads to low performance in school and deaths due to asthma attacks. Mr. Chairman, I would like to submit a summary of the report's findings as a part of the record.

The availability of reasonably priced insect control products, including many of the pesticide products currently under review by the EPA under FQPA, is critical to keeping the cockroach population under control. Insects like cockroaches can become immune to pesticides if only one or two products are used. Therefore, we need a variety of products available. If the Food Quality Protection Act is not implemented using good science and good sense, statistically valid use data and an understanding of real exposure, then there is a great likelihood that valuable products will be lost.

The benefits of public health pesticides must be balanced with the risks from the use of these products for other purposes.

In conclusion, let me say that Congress did not intend for EPA to rush to judgment on pesticide decisions. Yes, there are new standards, but there is also the need for a sound approach to the decision process based upon good science and good data. Exaggerated and inaccurate assumptions are not good science or good data. Best guesses are not acceptable.

EPA has an obligation to ensure that safe, public health pesticide controls continue to remain available. H.R. 1592, legislation that I

have cosponsored with Representatives Pombo, Condit and Boyd, provides needed direction to EPA for a logical and transparent implementation process based on reliable science, as Congress originally intended when we passed this legislation in 1996.

It does not change in any way the health and safety standard established by the Food Quality Protection Act. While I remain hopeful that EPA will implement FQPA in science-based, reasonable manner, I believe Congress should also be prepared to move H.R. 1592 to ensure that the public health benefits of pesticides are retained and that our food supply remains abundant and affordable to all Americans, and to make certain that it is safe. I would like to thank you, Mr. Chairman, for having the opportunity to testify before the committee, and at this time I will entertain any questions you might have.

Mr. GOODLATTE. Thank you, Mr. Towns. Mrs. Clayton, do you have any questions?

Mrs. CLAYTON. I don't have any questions. I just want to assert that his comment that he represents an urban area, Brooklyn, NY, is not completely inaccurate, but it is not the whole statement. He is in Brooklyn by way of North Carolina. I happen to represent his birthplace, or did, and know his family. So, I want to welcome the North Carolinian who has become a New Yorker.

Mr. TOWNS. Thank you very much. Also, I have another interest. The people in Brooklyn also eat, so I want to make sure the food is safe. [Laughter.]

Mr. GOODLATTE. The gentleman from California.

Mr. POMBO. Thank you, Mr. Chairman. Just for the record, as the chief co-author of H.R. 1592, I wanted to ask Mr. Towns a question. Do you at all, in your deliberations over this legislation and the many months that we have worked together on this—do you care about children at all? Do you care about poisoning children? Would you do anything that would poison your kids, grandkids, your constituents?

Mr. TOWNS. Absolutely not. And, of course, you mention grandchildren. I have two granddaughters, one 8 and the other one is 4, and they are very special. Aside from that, children in general are very, very special, and I think we have an obligation and responsibility to protect them all. But aside from that, I think we have an obligation to protect everybody, and I think that a safe food supply is very, very important. And that is the reason why I am so involved with this legislation, because I think it does that, and I think it makes it possible for it to be safe. And I am hoping to be able to move it through, and hope that maybe as we go along we will pick up additional sponsors.

Mr. POMBO. I thank the gentleman for coming here and testifying. More importantly, I thank you for all the work that you have put in to protect those grandchildren of yours. Thank you very much.

Mr. TOWNS. I thank you for your help, too. Thank you very much.

Mr. GOODLATTE. The gentleman from Texas.

Mr. STENHOLM. No questions, but I appreciate your contributions.

Mr. TOWNS. And it is within the budget, too. [Laughter.]

Mr. GOODLATTE. Well, Congressman Towns, I want to thank you as well for your contribution and for helping to point out that the issues that this committee deals with affect all Americans no matter where they live, and that good, high quality food is vitally important, and the process by which we produce that is vitally important and, also, the contribution which the production of pesticides that are used in agriculture makes in making sure that those same products can affordably reach the market for people who can't afford to spend a lot of money but face a very serious problem in urban areas, and really in every area of the country, in dealing with conditions that make living very unpleasant when you have to fight insects and rodents and so on. So, your linking what we do on this committee with the world as everyone else knows it and sometimes thinks that what they get from the grocery store came from the back room and not from the agricultural areas that Congresswoman Clayton and I, and every other member of this committee represent, is a valuable contribution, and we thank you.

Mr. TOWNS. Thank you very much, Mr. Chairman, I look forward to working with you.

Mr. GOODLATTE. The timing of this hearing, as I noted earlier, is unintended, but certainly very significant in light of the developments that took place yesterday with the Environmental Protection Agency, and there is no coincidence whatsoever between the fact that I am sitting here and I have a lot of apples here setting next to me, and I just want to make it clear to everybody here that I view these actions as very serious, that it is very important that people understand there are a great many people, myself included, who want to assure the American public that they have a safe food supply, including things as healthy to eat as apples—and an apple a day will keep the doctor away, it will not cause the doctor to need to visit you—and I want to make sure that folks——

Mrs. CLAYTON. You are not going to eat all those apples?

Mr. GOODLATTE. No, I am going to pass them around and let you enjoy them. I have mine here. We usually have peanuts and everything else here, but today is "Apple Day" at the committee.

At this time, I would like to recognize the gentleman from Texas, Mr. Stenholm.

Mr. POMBO. I just have a comment. Is it OK if we observe someone else eating the apples, to see if they are OK afterwards? [Laughter.]

Mr. GOODLATTE. Yes, that is your choice. The gentleman from Texas.

Mr. STENHOLM. I thank the chairman very much for yielding, and thank you for holding this very important hearing today on public health issues. And I couldn't have said it better myself than Mr. Towns, just a moment ago, in putting in proper perspective that which we are about today.

I also appreciate this opportunity to discuss the EPA's recent announcement to cancel certain uses of two organophosphates, OPs, prior to completion of the process set up by the Tolerance Reassessment Advisory Committee, or TRAC.

It has been almost a year and a half since the Vice President sent a memorandum to EPA and USDA instructing them to follow four basic principles. Mr. Pombo just outlined them a moment ago,

let me reiterate them: (1) ensure a transparent process; (2) let sound science guide the decisionmaking process; (3) stakeholder input; (4) a reasonable transition for agriculture. I strongly support those sound principles.

Shortly after the memorandum was released, the TRAC was created to allow all stakeholders to participate in the discussion surrounding FQPA implementation, and this just bugged the hound out of some folks that had had the field to themselves prior to this decision.

There were many in the Agriculture Committee who believed that the TRAC was nothing more than an empty promise, and this would be no different than their past dealings with EPA. Congressman Marion Berry and I encouraged these folks to take advantage of this opportunity. I believe the Members from the agriculture community felt that they were valued participants in this important process during the past year.

While there were sometimes disagreements in the TRAC meetings, there was also tremendous progress. In any case, participants left the meetings with a better understanding of the issues under consideration and the views of those who were not in agreement. Two of the most important decisions made by the TRAC were to put the key science policies out for notice and comment, and to set up a clear transparent and understandable process to be followed as risk assessments were being done on OPs.

I cannot emphasize too strongly the importance these two acts had on agriculture. EPA gained immeasurable credibility by allowing for an open, understandable and inclusive process. For the first time in 20 years in the Congress, I found myself saying good things about EPA and meaning it, and sincerely believing what I meant.

Yesterday, however, EPA Administrator Carol Browner announced EPA's intent to cancel uses for azinphos methyl and methyl parathion. Coincidentally or not, this announcement took place the day before FQPA's third anniversary. Ms. Browner's announcement occurred just two hours before the technical briefing on one of these chemicals was to take place, and after an impressive ad campaign was released by the environmental community to scare parents and children about the safety of our food supply. The ad by the environmental community attacked EPA for failing to take action—translation: No cancellation of OPs.

I never cease to be amazed by the fact that those who speak out against utilizing technology in food production usually do so with a very full mouth.

To those of you who use these irresponsible scare tactics, I say "shame on you", and specifically comments like showed up in the New York Times earlier this week, "They are going"—they, meaning EPA—"out of the way to say, 'eat this stuff,' " even though they are banning it next year. That is from Mr. Ken Cook, president of the Environmental Working Group.

If there was anything unsafe about these apples or pears, would we be eating it? Would we want our children to eat it? Would anyone? I have made it very clear throughout my life on this committee and before, that if sound science dictates that anything that we are using in the production of food should be banned, it ought to be banned immediately, but it should be done based on sound

science. It should be based on the conclusion of a majority of sound science, not some individual scientist or organization who reaps tremendous benefit from creating sensationalism in making that determination.

From the beginning of this process, many of us in agriculture have said we should follow the process using sound science. If it is determined that a chemical poses an imminent hazard, let us take it off the market. Find anyone in agriculture that says anything other than that.

After following the process, if sound science dictates that we must transition away from a chemical, we have stood ready to work with EPA, USDA, and interested stakeholders to find the best way to do this.

Yesterday's announcement by EPA does not follow either scenario, and that is why I and others are so upset with this announcement. The TRAC laid out a six-step process to be followed. Yesterday EPA announced its intent to cancel uses of methyl parathion which is just now in step 5. It is my understanding, because of the time pressures on USDA to finish their review of the risk assessment, they were not able to do as much grower outreach as necessary.

There are also two key science policies, 99.9 and 10X, that are yet to be decided by EPA, that could have a significant impact on the risk assessment of one, if not both, of the OPs mentioned yesterday in EPA's press conference.

Now, I may be just a cotton farmer from west Texas, but common sense tells me that somewhere along the way a commitment to the process and sound science were tossed aside in favor of political whim. And, interestingly, just last Saturday, the President of the United States, in his message to America, said "America's farmers look ahead to this year's harvest, what should be a time of reward and satisfaction, instead is becoming a time of disappointment." Now, I am not sure he meant with that statement the problem that we perhaps are failing now, but anyone reading that statement would note that when you make an announcement of this nature right in the middle of harvest of apples and pears, et cetera, you might perhaps affect the bottom line of farmers. And I choose to say that is what he meant, but one of his Department leaders chose not to acknowledge that.

American farmers have already been hit by the lowest prices in decades, diminishing foreign markets, and devastating drought. EPA's announcement came at the heart of harvest season and could have serious impact on fruits and vegetables treated with either of these chemicals.

Finally, while I intend to continue to work with EPA, USDA, and any interested parties in FQPA implementation, my faith that we will be able to solve issues administratively is not as strong as it was a year ago, or even just a month ago, or even 4 days ago. For that reason, I would like to ask my colleague from California, Mr. Pombo, to add my name as a co-sponsor to his bill, H.R. 1592, the Regulatory Fairness and Openness Act of 1999.

I had felt that this EPA was giving a good faith effort to move forward in the direction that we were needing to go, but that was totally destroyed with the actions that were taken yesterday.

Again, Mr. Chairman, I thank you for holding this hearing. I appreciate having the opportunity to address these issues, and I, again, couldn't have said it better than Mr. Towns a moment ago—food supply needs to consider safety, affordability, and abundance. To those among us that believe you can ignore any one of those three in the policies that this country follows and the importance that we have to the rest of the world, any one that believes that America and the rest of the world can be fed with abundance of food, without using technology, are wrong. It cannot be done, and I defy anyone to come before this committee at anytime and suggest that it can. In order for us to have the safest food supply at the lowest cost and the most abundant quantity and the best quality, we must use technology and we must use it safely. And somehow, some way, we have got to stop listening to those who would sensationalize the safety of our food supply for personal gain—for personal gain—and we must be able to find ways to use consensus science.

Mr. Chairman, that is what you and this committee have been trying to do. Mr. Berry and I have been playing a role—and he will speak for himself regarding where we are today—but we continue to have a problem because of the unwillingness of some to follow good science and a sound procedure, and that is a potentially big problem. I thank you for your indulgence, Mr. Chairman.

Mr. GOODLATTE. I thank the gentleman for his well thought out comments. I just wish he felt more strongly about it. [Laughter.]

The gentleman from California, Mr. Pombo.

Mr. POMBO. Mr. Chairman, I just wanted to respond to Mr. Stenholm briefly, and thank him for lending his name to the legislation, but I wanted to point out that Mr. Stenholm, I believe, has acted extremely responsibly and cautiously throughout this entire debate, and I have had the opportunity to talk to him about my concerns and my problems, and have been told, too, that Mr. Stenholm felt that the process could work, and that we should hold off on the legislative fix. And I appreciate what you had to say and, as usual, I think it was very important and well thought out. Thank you.

Mr. GOODLATTE. I thank the gentleman. The gentleman from Illinois, Mr. LaHood.

Mr. LAHOOD. Mr. Chairman, thank you. Mr. Stenholm, I would love to have you be a co-sponsor of my bill. It is not that dissimilar to Mr. Pombo's bill. It would be a great addition to my bill if you would cosponsor it. I would love to have you, Charlie.

Mr. STENHOLM. I would be happy to put my name on your bill.

Mr. LAHOOD. Thank you very much, glad I asked. Thank you, Mr. Chairman. [Laughter.]

Mr. STENHOLM. Whatever it is I cosponsored.

Mr. LAHOOD. It is a very good bill, and it goes right along with what your statement was, and it is very similar to Mr. Pombo's bill, and I am glad to have you as a cosponsor. Thank you very much.

Mr. STENHOLM. I am very familiar with your bill, and I am happy to join and cosponsor, and seeing if we might not be able to move the legislative process because the administrative process broke down in a very significant way yesterday, and if you would continue to yield for another point——

Mr. LAHOOD. Yes, sir.

Mr. STENHOLM. It wasn't but just a few weeks ago that EPA kind of got their hand slapped regarding clean air in that they were going too far in the interpretation of what Congress meant, and I think they have done exactly the same thing again yesterday. And I think that it is very important now, if we are not going to have the administrative good faith efforts to move us forward, that it is important for us to look at any and all legislative solutions. And I don't look forward to going down that route, but I am pleased to move down that route now and add my name to your bill, Mr. LaHood.

Mr. LAHOOD. Thank you, Mr. Stenholm. Mr. Chairman, I would associate myself with Mr. Stenholm's comments. I don't think anybody on the committee could have said it any better than you have, and I appreciate very much your statement here today. Thank you.

Mr. GOODLATTE. I thank the gentleman. I want to second the comments of the gentleman from Texas as well. The statutory deadline for the EPA to evaluate the first one-third of all pesticide tolerances occurred today and, as the gentleman from Texas pointed out, the EPA was making progress in this area. They apparently have met the statutory requirement that they evaluate one-third of the pesticides, but I don't see how there was any further need to take the drastic actions on two widely used and agriculturally important pesticides that we witnessed yesterday, the hasty decision to act upon these products without finalized science policy seems to be largely guided by political desires.

Concern has surfaced that these public and highly visible decisions could have a dramatic effect on consumer confidence since much of this year's crop has already been treated and harvested. Without an imminent hazard presence, a decision to announce such dramatic restrictions for two widely used pesticides seems unwarranted. The tolerance reassessment process has largely been undermined and shortcircuited by these decisions. Decisions to greatly restrict uses have been finalized prior to completion of critical scientific policies. Interim policies that have not completely gone through the notice and comment period are negatively impacting the decisions of the EPA. Without finalized policies in place, the system loses credibility, consistency and fairness.

In summary, what has emerged over recent days was the decision by EPA to have at least two significant examples of risk mitigation accomplishment opposite the 39 organophosphate insecticides in time for the August 3 deadline. This decision was set and the course charted to meet that goal, notwithstanding the fact that not all scientific studies on the two subject chemicals had been fully evaluated by EPA and incorporated into the risk assessment, more science studies are in progress, science policies that could significantly impact the risk assessment of the two subject chemicals have yet to be finalized by EPA, important grower concerns have not been included in the process, at least two recent meetings were held in the Midwest by the EPA, as was pointed out by the gentleman from California, with the environmental community that did not include major representatives from the effective grower community. Many of these same environmental groups have recently announced their withdrawal from the Tolerance Risk Advi-

sory Committee, which was formed to facilitate multi-stakeholder discussion of the tolerance setting process.

Perhaps the most intolerable and repugnant issue of all is that registrants were forced to the bargaining table and found themselves part of a rush to judgment in order to, I believe, contribute to a perception of further achievement by the August 3 deadline. This occurred despite the fact that the risk assessment and mitigation phase sixth step that was developed by the TRAC, with full endorsement by USDA and EPA, would be totally subverted and circumvented in the process.

Data call and authority is clearly vested in the EPA under FIFRA. To date, such authority has been blatantly ignored and abused. As we have seen over the last 3 years, the EPA has hidden behind their veil of disarray and confusion and stood firm in claiming that all the data needed was already in hand.

Just within the last several weeks, the EPA has exercised its authority in a limited fashion for data requirements established under the FQPA. What good does this do for those products that the EPA had already passed muster on yesterday? Both major registrants already committed to perform additional studies and, in fact, new data was already being generated at the time of the announcement. How can the process completely ignore this?

Undue delay and long, drawn out process has never been what we have called for. However, with no imminent present, expedited decision for the sake of political gain is intolerable.

We have a vote on the floor. I would suggest that the subcommittee recess, and we will come back to hear the second panel.

[Recess.]

Mr. GOODLATTE. The subcommittee will reconvene. We are now pleased to welcome our second panel, Mr. Richard Rominger, Deputy Secretary of the U.S. Department of Agriculture; Mr. Peter Robertson, Acting Deputy Administrator, U.S. Environmental Protection Agency; Mr. William Lovelady, chairman of the board, National Cotton Council, Washington, DC; Dr. Wayne Carlson, vice-president of regulatory affairs and field development for the Bayer Corporation, Kansas City, MO, accompanied by Mr. Jay Vroom, president of the American Crop Protection Association.

Mr. Rominger, we are glad to have you with us and, as you know from your many visits to our committee, your statement will be made a part of the record, and we welcome your testimony at this time.

STATEMENT OF RICHARD ROMINGER, DEPUTY SECRETARY, U.S. DEPARTMENT OF AGRICULTURE, ACCOMPANIED BY MR. KEITH PITTS, SPECIAL ASSISTANT TO THE DEPUTY SECRETARY

Mr. ROMINGER. Thank you, Mr. Chairman. I am pleased to be here to talk to the committee about the U.S. Department of Agriculture's role in the implementation of the Food Quality Protection Act. I also have with me today Mr. Keith Pitts, who is my Special Assistant on this subject, and is here to help me answer any questions.

I would like to just remind everyone that I have been at the Department now for over 6 years as Deputy Secretary, but I spent

most of my life on the agriculture side of this issue as a farmer in California, and so as a practicing farmer I used pesticides for quite a number of years. I have three sons who are now farming and continuing that tradition. I also have four grandchildren, and I also want to make sure that this food supply is safe—and I would be happy to eat one of those apples, too, if you are going to pass them around.

I also spent almost 6 years as director of the California Department of Food and Agriculture before there was a CAL EPA, when the department regulated pesticides in California and we were involved in putting together the pesticide regulatory program in that state. So, I think I have a good understanding of both the agricultural side and the government/public side of this issue.

I have a few remarks on public health issues that I could make at this point, but I would just submit those for the record, if you would prefer, and then be available to answer questions, or I could make a few comments about USDA's involvement in some of the public health issues.

Mr. GOODLATTE. We will take your opening remarks, and then hear from the other panelists, and then come back for questions.

Mr. ROMINGER. Thank you.

[The prepared statement of Mr. Rominger appears at the conclusion of the hearing.]

Mr. GOODLATTE. Next, we are pleased to welcome Mr. Peter Robertson, of the EPA.

Mr. Robertson.

STATEMENT OF PETER ROBERTSON, ACTING DEPUTY ADMINISTRATOR, U.S. ENVIRONMENTAL PROTECTION AGENCY

Mr. ROBERTSON. Thank you, Mr. Chairman. We appreciate the opportunity to be here today. With me is Jim Aidala, the Associate Assistant Administrator from the Office of Prevention Pesticides and Toxic Substances, and Steve Johnson, who is the Acting Deputy Assistant from that same office. With your permission, I will briefly summarize my remarks and submit my full statement for the record.

Before I begin my testimony, however, I would like to say a few words about your late colleague, Representative George Brown. Mr. Brown was one of EPA's earliest and strongest supporters, and we at EPA will always owe him an enormous debt of gratitude. Virtually every major piece of environmental legislation bore his stamp in one way or another, and America is the better for it. The tireless dedication and years of experience that he brought to these issues will be sorely missed by all of us.

In light of yesterday's announcement of agreements on two organophosphate insecticides and today's passing of the first major FQPA milestone, I would like to address our progress in implementing FQPA as well on public health pesticide uses.

Public health pesticides play an important role in our society, helping to protect us from disease vectors such as mosquitoes, ticks, cockroaches, and rats. FQPA's requirement that EPA consider the aggregate risks of all nonoccupational exposures to a pesticide when reviewing tolerances has placed greater emphasis on evaluating non-dietary exposures, including those from public

health uses, and it has raised concerns about how EPA is considering public health uses and how we are evaluating non-dietary pesticide exposures.

Let me assure you, Mr. Chairman, that EPA takes these concerns very seriously. EPA is working closely with HHS and USDA to assure that we are appropriately considering public health pesticides as we implement the law. EPA has appointed a Public Health Coordinator to facilitate interagency communication and coordination. We are sharing with HHS all risk assessments for pesticides with public health uses in order to improve our risk assessments, and we are working to put in place a Memorandum of Understanding to formalize this interagency cooperation to attain our common goals.

We have been working for a number of years to improve our databases and methods for evaluating non-dietary exposures, including those from residential pesticide uses. We have used a number of tools, including data call-in, voluntary cooperation with industry groups, and EPA supported research efforts to improve our data and risk assessment methods.

Taken together with the scientific policies that are subject to the public notice and comment process laid out at the TRAC, these activities are putting the agency on a sound scientific footing to evaluate all sources of pesticide exposure, as required under the FQPA.

Let me turn now to the broader FQPA implementation issues. Today is an important landmark in the implementation of FQPA, as you and other members of the subcommittee noted. It marks the third anniversary of enactment, and also the first major milestone in the statute, the deadline for reassessing the first third of tolerances. I would like to use this opportunity to outline briefly where we stand, and also to discuss yesterday's announcement.

First of all, I am pleased to announce that EPA has met the first tolerance reassessment deadline, reassessing 3,290 tolerances. Relying on the four principles that underlie the TRAC process—transparency, sound science, stakeholder involvement, and a reasonable transition for agriculture—we have been able to meet able to meet this deadline and base our decisions on sound science and an open consultative process.

Our experience with the TRAC pilot process for refining organophosphate risk assessments has also shown us the value of transparency and consultation. This public process has yielded important new information that has greatly improved our risk assessments. Similarly, the public process for revising key science policies is helping to ensure that our assessments and policies are grounded in the best available science.

As you know, yesterday the Administrator announced cancellation agreements and risk reduction strategies on two organophosphates, azinphos methyl and methyl parathion, that will significantly reduce risks, especially dietary risks to infants and children. These measures include elimination of a number of uses, particularly uses of methyl parathion on fresh fruits and vegetables. These uses of methyl parathion represent 90 percent of the estimated risks to children. Other uses will be modified, including reductions in tolerances and other measures to reduce risk.

These steps will greatly reduce consumer exposure, while leaving farmers with a wide array of viable crop protection tools.

FQPA was a challenge to all of us to do better, to provide an extra measure of protection for American consumers, and that is precisely what these actions will do. At the same time, and as Administrator Browner and Deputy Secretary Rominger noted yesterday, we still believe that our food supply is the safest in the world, and this administration continues to encourage all Americans to eat a well balanced and varied diet, particularly one rich in fruits and vegetables.

I also want to assure the members of this committee, as well as growers and food processors, that food already treated with these pesticides will be fully acceptable in commerce. As the Administrator said yesterday in her announcement, "These actions we are taking today evolve from the tough new requirements of the Food Quality Protection Act, and under no circumstances should be used to challenge the safety of our existing food supply, or even a particular fruit or vegetable."

The TRAC process has been a useful one for both EPA and USDA. I want to assure you that we have been faithful to the TRAC process and the four principles that underlie it. These actions were based on sound science and the best available data. The risk assessments went through the public comment and USDA review process, as outlined at the TRAC. And EPA and USDA have been consulting with our stakeholders, including growers, to make sure that these actions will not leave them in the lurch.

These principles really come down to using common sense. Take appropriate steps when evidence shows that they are necessary, but be mindful of the impacts our actions can have. The measures announced yesterday were the result of a careful and deliberative process, but the time had come for action.

Mr. Chairman, as many members of this committee have pointed out, farmers are the first ones to say that if there is real evidence of a product that poses unreasonable risks, we shouldn't be using it. We believe the steps announced yesterday meet that test, and we want to continue working with you, the growers, and the pesticide industry, and all other parties, to make our food supply even safer. Thank you, Mr. Chairman.

[The prepared statement of Mr. Robertson appears at the conclusion of the hearing.]

Mr. GOODLATTE. Thank you, Mr. Robertson.

I am now pleased to welcome Mr. William Lovelady.

STATEMENT OF WILLIAM LOVELADY, CHAIRMAN OF THE BOARD, NATIONAL COTTON COUNCIL

Mr. LOVELADY. Thank you, Mr. Chairman. My name is Bill Lovelady, and I am a cotton farmer from the El Paso Valley of Texas. As a farmer, I take seriously my role as steward of the land and our resources. I am also a father, and I want you to know that my children were raised eating safe and nutritious U.S. grown fruits and vegetables—maybe not as many as they should, but we tried.

Thank you for the opportunity to speak on behalf of the members of the National Cotton Council, and thank you for your continued interest in the implementation of the Food Quality Protection Act.

It appears EPA has abandoned sound science and replaced it with political science. That does great disservice to farmers, to food processors, and consumers, by undermining confidence in our Nation's outstanding production, regulatory and delivery system.

In response to our concerns, Representatives Stenholm and Berry contacted Vice President Gore over a year ago, and the Vice President issued a memo directing EPA and USDA to work together, to be guided by four principles—sound science, transparency, stakeholder input, and transition. One result of that memo was the formation of the Tolerance Reassessment Advisory Committee. I serve on the TRAC.

Although there has been some criticism of the process, my personal opinion is that TRAC has been very useful and has made significant progress for several reasons. First, the TRAC has served as a useful vehicle for producers and other interested parties to participate in the Food Quality Protection Act implementation process. Second, the TRAC meetings have resulted in an increased role for USDA. Third, EPA has identified at least nine science policy issues that are important for FQPA implementation. Finally, EPA has developed a six-step pilot program for reassessing tolerances of OPs.

Mr. Chairman, to be candid, the decisions announced by the EPA Administrator yesterday have jeopardized the progress of the TRAC process. Any credibility or trust which may have been developed towards building a cooperative and consensus based process for implementing FQPA has been seriously compromised.

EPA has decided to target methyl parathion and azinphos methyl and to cancel and mitigate some of their uses. Fruits and vegetables are going to be the most severely impacted. EPA made these decisions despite the fact that several key science policies identified in the TRAC discussions and pertinent to these compounds have not been completed.

The final decision on application of 10X children's safety factor is not expected until March of 2000, yet EPA is applying the full 10X factor to methyl parathion in spite of neurotox studies submitted by the registrant. Other pertinent science issues which have not been resolved are the use of human data and the 99.9 percentile data confidence interval.

As I mentioned earlier, a six-step pilot process was established to guide review of the OPs. In the case of methyl parathion, phases 5 and 6 were totally disregarded. EPA announced final decisions on this product before USDA completed its review. The Agency made a public announcement yesterday, before the technical briefing was conducted, and affected users were not consulted as these decisions were being made.

Mr. Chairman, I am concerned that any hope of future cooperation and progress with EPA concerning FQPA implementation has been seriously compromised. The efforts of the TRAC may have been wasted. I am also concerned that representatives of the so-called environmental community walked away from TRAC. A dangerous precedent has been established. A well defined transparent

science based process is critical to the implementation of this important legislation. Safe, effective crop protection products are vital so that farmers can continue to provide safe, affordable food and fiber for consumers.

Again, thank you for the opportunity to provide comments on these issues.

[The prepared statement of Mr. Lovelady appears at the conclusion of the hearing.]

Mr. GOODLATTE. Thank you, Mr. Lovelady.

I am now pleased to welcome Mr. Wayne Carlson, of the Bayer Corporation. Mr. Carlson, welcome.

STATEMENT OF WAYNE CARLSON, VICE-PRESIDENT, REGULATORY AFFAIRS AND FIELD DEVELOPMENT, BAYER CORPORATION

Mr. CARLSON. Thank you, Mr. Chairman, ladies and gentlemen. My name is Wayne Carlson. I am vice-president of regulatory affairs and field development for Bayer Corporation's Agriculture Division, headquartered in Kansas City, MO. I am pleased to have the opportunity to discuss this issue with this committee.

Bayer Corporation is one of the manufacturers of azinphos methyl, an organophosphate insecticide widely used for the control of insects infesting tree crops. It also is used to a lesser degree in cotton and several other crops.

Azinphos-methyl is procedurally the furthest along of the products being evaluated under the step-wise process laid out in the TRAC. I have been asked to come before you today to describe some of our technical and procedural observations and experiences as our product has gone through the FQPA process.

I would like to group these comments into three areas—first, science and policy issues; second, the complexity of the process; and, third, the critical importance of carefully implementing FQPA according to the TRAC process.

Relative to science and policy, experience with our product clearly shows how critical science and policy issues are to the FQPA implementation process and to future availability of pest control products. The importance of science and policy were recognized early by the FQPA Implementation Working Group, the IWG, a coalition of 66 commodity, grower and pesticide-related organizations.

In its April publication called The FQPA Roadmap, IWG outlined eight critical science policy areas which needed to be clarified prior to the FQPA decisionmaking process moving forward. This list of science policy issues has grown to nine as a result of further investigation in the TRAC process. There are now some 20 individual science policy papers generated, detailing issues in these nine areas. Only one of those has been issued as final. Several are only scheduled and won't be issued yet for some time. These science policies represent the foundation of decisionmaking under FQPA. Without them, decisions are, at best, interim, which could have a negative effect on some user groups.

There has been much discussion surrounding the use of default or screening level assessments for products being used while these science policy issues are being finalized. This committee saw during the April hearings, the differences between a dietary risk assess-

ment based upon default assumptions versus a refined risk assessment, a difference of 10,000 percent of the risk cup versus about 130 percent of the risk cup for the most sensitive subpopulations in the FQPA dietary risk assessment for azinphos methyl.

That 130 percent is influenced by other science policies still under debate and discussion, even with the refined dietary exposure values contained in the assessment. In fact, there are 11 policy documents, of the previously mentioned 20, plus the use of human data, that will ultimately influence the decisions on products like azinphos methyl. Bayer Corporation has recently submitted two human studies to EPA and California. California has reviewed and accepted the results of these studies in its risk assessment process. U.S. EPA still has not, and we are awaiting its policy decision.

The most critical of all of the policy decisions in question is the 99.9 percentile policy. The 99.9 percentile is considered by some to be a default or screening level value; by others, it is considered to be a regulatory point. The azinphos methyl risk assessment involving dietary exposure showing about 130 percent of the risk cup for the most sensitive subpopulation becomes only about 80 percent at the 99.75 percentile; 35 percent at the 99th percentile; and only about 14 percent at the 95th percentile, the level normally used to establish significance in scientific studies and the level at which FDA regulates food additives. Use of human data could even further reduce these values several fold. In short, it is entirely possible that one of several policy decisions could result in a risk level well below that of the current 130 percent.

This brings me to my second concern, the complexity involved in the FQPA process. FQPA requires that all available and reliable data be employed in the process. In the case of azinphos methyl dietary risk assessment, 52 crops were included, with 261 specific food forms, each one requiring separate scientific judgments for application of the 133,708 datapoints and 40 separate processing factors. This just includes dietary exposure from food. We need to keep in mind that FQPA requires food exposures be combined with water exposures and with exposures resulting from applications in the home, in restaurants, et cetera, for chemicals which are approved for such uses, into what is called an aggregate risk assessment for a single chemical. Finally, exposure from that chemical needs to be added to others, if they are deemed to share a common mechanism of toxicity, into what is called a cumulative risk assessment.

How to conduct a cumulative assessment is very complicated, and you can imagine a critical factor in determining the future of families of important pesticides. If it is done too hurriedly or in an overly conservative manner, pesticide availability will suffer needlessly.

In addition to what we have learned relative to the critical aspects of the science policy issues and the complexity involved in the proper exposure and risk assessment, we have learned the importance of adhering to the process of FQPA implementation as outlined in the TRAC.

In their April testimony before this committee, Jim Aidala and Keith Pitts described a six-phase pilot process which, among other

things, was to "Provide for public participation on risk mitigation measures and practical transition strategies."

Azinphos-methyl, the product furthest along in the process, has just completed phase 5, a phase in which risk mitigation proposals were to be submitted by the registrant and other interested parties. phase 6 was to allow EPA and USDA to work together on risk management strategies. Near the end of the phase 5 period, Bayer Corporation found itself in intense negotiations on risk mitigation issues. It was very difficult, in a limited amount of time, to contact the many interested grower and user groups to get their full input to be sure that their needs were being considered in the risk-benefit assessments required under FIFRA regulated mitigation proposals. It is critical that the sixth phase of the process be included, a process of up to 60 days wherein EPA, along with USDA, work together to develop risk management strategies, to assure that the users' needs are not ignored.

In conclusion, despite the complexities of FQPA, it is still a good law, one which requires us to bring our best science and data to the process of regulating pesticides. It also is really a powerful law, and it must be implemented with responsibility and reason. EPA and USDA have a responsibility to use the best science available and consult with growers and applicators. We favor legislation that furthers this objective. We have a safe, abundant, and economical food supply. We must act carefully to be sure that it is even safer, more abundant, and more economical in the future.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Carlson appears at the conclusion of the hearing.]

Mr. GOODLATTE. Thank you, Mr. Carlson.

Mr. Robertson, let me ask you—I have a copy of the Memorandum of Agreement between the Environmental Protection Agency and Signatory Registrants, regarding the registration of pesticide products containing azinphos methyl. On page 14 of that agreement, there is a provision that says "All the signatories to this agreement agree that they will not challenge or provide financial or technical assistance to anyone challenging in any forum any of the provisions of this agreement."

First, I would like to ask you why you would put such a gag order in an agreement that you would have with anybody regarding an issue of trying to come to a conclusion about the beneficial or nonbeneficial aspects of any pesticide or other product that is being evaluated by the EPA?

Mr. AIDALA. Mr. Chairman, this is a fairly standard part of a voluntary agreement, given that if the agreement is that you are not going to exercise some of your rights under the statute, given that we are going the voluntary route, that is really what that is referring to. It is not any attempt to be a gag order or some of the other characterizations it may sound like.

Mr. GOODLATTE. Well, it sure sounds like the consequences of not doing so would be a violation of the agreement. I mean, to me, the purpose of the Environmental Protection Agency is to get at the truth, to find out whether a particular product is helpful, and we have already had some testimony and we are going to have more testimony, about how a lot of these products are very helpful, at

assuring that we have high quality, affordable and abundant food, and that we have high quality and safe food and pesticides for use in public places and types of uses that Congressman Towns testified to, and it would seem to me that if an agreement is entered into and somebody has reason to believe that it is not the best agreement in the interest of the public, that the EPA would not have a provision like that, attempting to shield from the public, from the Congress, from others who want to get at the truth of this matter, the ability of somebody who may have some information to shed on that, the right to challenge the agreement or the findings therein, or to provide financial support to a group or organization who may be engaged in doing just that. Can you defend the clause in this agreement?

Mr. AIDALA. Again, this type of provision is designed to be the substitute for what otherwise under the statute is all the rights and opportunities people have in other cancellation proceedings. Since this is a voluntary cancellation agreement, the idea is that you are then basically having this be the substitute for all the kinds of things that registrants have and, in some cases, have over the years quite rightfully exercised their rights under the statute. It is not an attempt to say, for example, that this particular registrant or any other could not provide information, could not state the kinds of things that they are stating about whatever the factual case is. In those kinds of matters, for example, we would be FOIA'd with all of our information, what were our assessments and whatnot, and obviously we would make those public too, as a public agency.

In terms of a particular sort of history of these kinds of provisions and these kinds of agreements, I would ask that we could respond to the record because our General Counsel's Office obviously has more particular experience and expertise in this matter.

Mr. GOODLATTE. Well, I think it is a very serious matter because the way I read this, it says "All signatories to this agreement agree they will not challenge in any forum any of the provisions of this agreement."

Now, to me, one of the principle purposes of this hearing is to determine whether or not this agreement was made in the best interest of the public, and that is exactly what I think would be wrong if we did not allow everybody participating in this hearing to freely challenge the agreement or any of the assumptions contained in that agreement. So, we would welcome a response in writing from the Counsel of the EPA about not only this agreement, but any others in which an agency dedicated to protecting the public and promoting the use of proper scientific procedures to get at the truth about these matters wouldn't have language where effectively they would try to silence somebody doing just that.

Mr. AIDALA. Again, Congressman, it is certainly no attempt to silence people. For example, in this kind of forum, it really is, as I am told by counsel, that it is a fairly standard part of these kinds of agreements. And, again, I would ask that we get back to you for the record. But, certainly, for example, this is a forum, in terms of any forum, and we would welcome any and all discussion, as obviously we have already engaged in so far this afternoon, and I am sure we will continue.

Mr. GOODLATTE. Then you ought to change the language in your agreement, and not make those who sign those agreements feel intimidated by them.

Let me ask Mr. Carlson, do you think the TRAC process was followed in EPA's decisions that were announced yesterday? You or Mr. Vroom can answer that question.

Mr. CARLSON. As I mentioned in my testimony, Mr. Chairman, we thought the process was being followed through the end of phase 5. At that point we were confused and we thought that there was some deviation at least from what we expected to happen in a phase 6 step in the pilot process.

Mr. GOODLATTE. Your understanding is the process was shortcircuited, in other words.

Mr. CARLSON. Yes.

Mr. GOODLATTE. Can you tell us at this point in time what other products are available as substitutes for guthion and methyl parathion for apples?

Mr. CARLSON. There are some other products that have some of the same kinds of activity, but as I understand it from the apple growing industry, they don't control all of the insects that azinphos methyl does in particular, and, therefore, there are some potential holes in the insect control spectrum, especially in some areas of the United States.

Mr. GOODLATTE. Mr. Lovelady, would you like to comment on the same question?

Mr. LOVELADY. Mr. Chairman, I testified before this committee back in April on the oversight, and at that time I said that I thought that the process was working well, and I was encouraged. Like I testified today, I think that that process has been shortcircuited, and while this is not one of those—neither one of these products are extremely vital to cotton, they are useful, and we view this as a deviation and a bad precedent to have been set, because we do not have answers to all of the science policies that are out there. And, in fact, the 10X is not even scheduled to be in until March of 2000.

So, I would have to say that I think we have shortcircuited the process, and I think that it sets a very bad precedent for all the future tolerances.

Mr. GOODLATTE. My time has expired. We may come back to this, but I know the gentleman from Arkansas is anxious to get on to something else. I want to recognize him right away. I thank him for his patience.

Mr. BERRY. Thank you, Mr. Chairman, and I thank you for holding this hearing. I will be very brief. I cannot begin to express my disappointment in the way that this process appears to have broken down, and the fact that EPA seems to be the only agency here that thinks it is working. And I think it is too bad that we have allowed this to happen and, again, let politics take over where good science should be in charge.

I have repeatedly asked EPA to show me the science on these various and sundry issues. I have yet to have any sound science presented to me, even though I have repeatedly asked for it.

Because of this, Mr. Chairman, I am going to also ask my distinguished colleague, Mr. Pombo, from California, to add me as a co-

sponsor of H.R. 1592, because I feel like the only option we have left to us is a legislative remedy rather than to try to work with EPA and deal with this in a responsible way. Thank you, Mr. Chairman.

Mr. GOODLATTE. I thank the gentleman. I now want to recognize the gentleman from California. This has been a very profitable hearing for you already. Keep it going and you may have a majority of the House before you know it.

Mr. POMBO. Send some more guys back in here. [Laughter.]

I thank the chairman for yielding to me. Mr. Carlson, I want to start with you. You state in your prepared statement that you are the vice-president of regulatory affairs and field development at Bayer Corporation's Agricultural Division.

When you develop a product, or want to keep a product on the market, who do you typically deal with at the Federal Government? Do you typically deal with EPA? Is that your regulatory body that oversees your operation?

Mr. CARLSON. Yes, that is the regulatory body that is responsible for the registration of pesticides.

Mr. POMBO. So the very essence of you, or your corporation, staying in business is held in the hands of EPA because they have the ability to take away your product from the market?

Mr. CARLSON. Yes, sir.

Mr. POMBO. The reason I ask that question, because I wanted to ask you about your voluntary agreement, and just how voluntary that was. Were all the changes voluntary—and I mean by voluntary, self-initiated on your part, as part of that agreement?

Mr. CARLSON. We have been involved in discussions and actions to make changes to our label for azinphos methyl for quite some time. We have initiated part of that really on a pro-active basis. These changes we made were part of that continuing negotiation and discussion about risk mitigation measures in order to bring our label into line to what we felt was reasonable and necessary to keep the critical uses for the growers.

Mr. POMBO. Is Bayer contesting any of the decisions that were made by EPA on the basis of incomplete science policies?

Mr. CARLSON. We are concerned about the process here, that is the main process.

Mr. POMBO. Well, I read your statement, and it appears to me that you do have some problems with the science policies that were followed, and I am wondering if you are contesting any of these decisions based upon those incomplete science policies.

Mr. CARLSON. We feel that the decisions could be revisited, and should be revisited, when the science policies are finalized.

Mr. POMBO. But a decision has come out in a very public way, a very hyped way, that obviously was heavily carried within the news media, and I think that—it appears to me that a decision has been made and, at the same time, from reading your statement, it appears that you have some real problems with the science that was used. Why are you not contesting that decision?

Mr. CARLSON. Well, as I mentioned, the decisions here are more mitigatory in nature relative to our product. Again, we have concerns, though, about future decisions being made that may be more

final in nature, particularly surrounding the policies that are still being discussed.

Mr. POMBO. I, like the chairman, am more than a little bit concerned that we have a regulatory body that holds the very essence, very existence, of your company in their hands, having you enter into a so-called voluntary agreement, and it appears to me that, for you, it is either "shut up or we will put you out of business," and I am concerned about that. I am very concerned about the policy as it has been laid out and, if this is not a precedent in terms of dealing with the regulated community, I would like to know in which other cases people entered into these so-called voluntary agreements.

Were you included in the recent meetings that occurred in Michigan and Wisconsin? Was your company included in those?

Mr. CARLSON. No, we were not.

Mr. POMBO. It was my understanding that that was a stakeholders meeting. Would you, or the people who use your product, not be considered as stakeholders?

Mr. CARLSON. I would hope that we would be considered a stakeholder.

Mr. POMBO. Can you tell me why you weren't invited?

Mr. CARLSON. I don't know the answer to that question.

Mr. POMBO. Can I ask the gentlemen from EPA why they were not invited, if it was a stakeholders meeting?

Mr. ROBERTSON. Mr. Pombo, those weren't our meetings, despite the characterizations that have been made by a number of members of the subcommittee here today. The meetings were sponsored by the World Wildlife Fund, Gerber Products, Del Monte Foods, and a number of other non-governmental organizations.

Mr. POMBO. Did you attend, or did anybody from EPA attend?

Mr. ROBERTSON. EPA did attend, yes.

Mr. POMBO. Mr. Rominger?

Mr. ROMINGER. Yes, we participated in those meetings, and were cosponsors of some of those meetings, and I think Keith Pitts could tell you more about it.

Mr. POMBO. You were cosponsors?

Mr. PITTS. Yes, sir. With those meetings in particular, we talked with growers in Michigan, apple growers in Wisconsin. We have also had similar meetings going on with peach growers in California and apple growers in southeastern United States, and what we are doing is, as growers do want to work with us on transition strategy, we will continue to meet with them. And we had a lot of interest in the Wisconsin and Michigan meetings because we did have an NGO group working with food processors and some grower groups, to talk about having discussions about transition, and we felt like it was a fruitful discussion for us to participate in.

Mr. POMBO. Mr. Chairman, my time is expired.

Mr. GOODLATTE. The gentleman from Virginia, Mr. Goode.

Mr. GOODE. Thank you, Mr. Chairman, and I want to thank you for holding these hearings. I know the Food Quality Protection Act is of much concern to growers in my district, just as they are in yours.

I would like to ask Mr. Robertson, if he is the appropriate person, the bill introduced by Mr. Pombo and with sponsors here on

this committee, could you give me two or three points as to your opposition to the bill, or have you taken a stand on it?

Mr. ROBERTSON. The concern that we have essentially, Congressman, is that the legislation potentially puts us at risk of getting into an endless do-loop, where we simply are forced to call in more data all the time, and are never able to reach a decision point. EPA would be unable to act even where the overwhelming weight of evidence showed us clearly that it was appropriate to act. I think that is, in short, EPA's most prominent concern with the bill.

Mr. GOODE. Give a specific situation that you have already gone through on a particular pesticide, that if this bill were in place, your action or decision would have been delayed a long time, if that would be appropriate to comment on a particular one?

Mr. AIDALA. Ironically enough, Congressman, there are some critics inside and outside the room who think we have done far too little on far too few, but I think, for example, it is hard to say, given the limited number of chemicals that have been through the process, what everyone thinks of and characterizes that as, that there are lots of examples out there—again, as we mentioned, the actions on the chemicals yesterday. And, fundamentally, I don't think that those would be so drastically affected. Our concern, as Mr. Robertson just said, is in terms of our inability, for example, to follow through with other provisions of FQPA, especially on cumulative assessment and aggregate assessment, I think, would be of most concern to us.

Mr. GOODE. I yield back the balance of my time, Mr. Chairman.

Mr. GOODLATTE. I thank the gentleman. The gentleman from Oregon, Mr. Walden.

Mr. WALDEN. Thank you, Mr. Chairman. Again, thank you for holding these hearings.

Dr. Carlson, I wonder what other products are available as substitutes for guthion and methyl parathion for apples? Would you address that?

Mr. CARLSON. To my knowledge, there are only a couple of products that control part of the spectrum of these materials. As I understand it, there are a couple of species of insects, particularly in the eastern fruit growing areas, where there are few, if any, substitutes for those products for.

Mr. WALDEN. What about out in the Northwest—Oregon, Washington—where I am from? We have concerns about pears and apples and cherries?

Mr. CARLSON. I know in that case azinphos methyl is widely used in conjunction with some of the integrated pest management programs out there as well, for codling moth control.

Mr. WALDEN. Are you still conducting studies on guthion and azinphos methyl?

Mr. CARLSON. Yes, sir, we are. We are continuing to generate new data on the product, as we have for some time.

Mr. WALDEN. Is it true at 99.8 percent level of regulation, the risk would be acceptable under this process?

Mr. CARLSON. Yes, that is true, that the dietary risk assessment under FQPA would be acceptable at 99.8.

Mr. WALDEN. Do you have confidence in the TRAC process to correctly implement and resolve the scientific issues that surround the

implementation of FQPA, after what you have witnessed the last few days?

Mr. CARLSON. I think the TRAC process is a good process, but it is going to take time. As I mentioned, the complexity of FQPA and all of the science that needs to be decided, it takes a lot of time to do that, to put that in place to be the foundation for the FQPA decisionmaking process to operate. I think a step-wise process like is laid out in TRAC would seem to me to be the proper way to go about that once the science is put together.

Mr. WALDEN. What, if anything, do you think Congress could do to help?

Mr. CARLSON. I think the main thing we would like to see would be to ensure that a process like was laid out in the TRAC is the process under which FQPA is implemented.

Mr. WALDEN. Mr. Chairman, my time has expired.

Mr. GOODLATTE. I thank the gentleman. I have a few more questions, and we are waiting to see if Mr. Stenholm wants to ask any questions of this panel.

Mr. Vroom, let me ask you, in response to the questions asked by Mr. Pombo, I detected some reluctance on the part of Mr. Carlson to go head-on on some of their concerns about this agreement they have entered into and the lack of completion of the process before action was taken by the EPA, and I wondered if you, as somebody who is not a direct participant in the agreement, might comment on that. Are these clauses in these agreements a problem of that nature?

Mr. VROOM. I am, Mr. Chairman, not familiar with all of the preceding voluntary agreements that have been established between the agency and other registrants previously, including those, many of which were done long before FQPA was passed, but it does seem to me like the words that you read out of this agreement and what Mr. Aidala explained in terms of the intent, there seems to be a pretty substantial disconnect there, and perhaps once we are able to talk with their general counsel, we can discover some compromise way, a better way to address that for the future.

I do think also that we probably have learned more about an expanded definition of the word "voluntary" in the last week, but at the same time I want to really emphasize a point that was in my submitted written testimony, and that is that we believe that the member companies of ACPA, Bayer and the others that were involved in this agreement yesterday resulting in the mitigation steps, were acting in good faith, as they always would when approached by EPA to consider mitigation steps, and as I think Dr. Carlson said, much of that kind of discussion had been ongoing on this particular chemical of theirs, with the agency before the recent weeks. It just happened that these two chemicals were the examples, if you will, that came forward at this moment in time, but most important was at least an equal measure of consideration by these registrant companies for the consideration of the interest of our common farm customers and trying to contribute everything that they could to averting a food scare during—a potential food scare—unnecessary if it might have occurred during this anniversary week of FQPA. So we need to catch our breath. We welcome your very specific interest and oversight in these questions, as well

as that of the other committees of jurisdiction, and looking at the very detail of these agreements, I think, sounds appropriate and important as we look for the path forward, and ideas like those embodied in Mr. Pombo's legislation and Mr. LaHood's legislation and the companion bill in the Senate that was just introduced last week, we think also have a lot of merit. But most importantly right now is that so far we haven't suffered the effects of a food scare. I hope that continues.

I have been invited to appear with Administrator Browner and Ken Cook this evening on PBS Television to discuss this further, so the last word certainly hasn't been spoken this week before the public on these issues, and that is of fair amount of importance to us, and I think to the grower community and all of your constituents of the Agriculture Committee.

Mr. GOODLATTE. Well, let me ask you this. What is the consequence to a company like Bayer, if they don't enter into an agreement like this?

Mr. VROOM. Well, the statutory authorities granted EPA in considering risks, and then the consequent actions would be either to determine if there is an imminent hazard, as defined under FIFRA and companion linkage to the food and drug law under the entire unified provisions of FQPA, or a slower process which would be a Notice of Intent to Cancel the company's registration and the companion tolerances to be revoked. And as has been referenced in the last 24 hours by Administrator Browner and others, that process could take longer.

Unfortunately, all of that, in our view, would have been circumvented had we been afforded the time that the TRAC process laid out, including phase 5 fully and phase 6 for these two chemicals to have gone through that more informal process that we had all negotiated and agreed to in the TRAC pilot process.

Mr. GOODLATTE. Mr. Robertson, you know how this appears to some of us is that you are coming up on a time frame when it is apparent that there are going to be a lot of products that are making their way through the process and are going to be accepted, and you are feeling pressure from some people who think you should be canceling a lot of these pesticides, and you pull somebody in and you force them to sign a so-called voluntary agreement, tell them in that agreement that they can't challenge it, face the consequences Mr. Vroom described if they indeed do challenge it, and I just have to wonder why you would circumvent a sound process in doing that, and then attempt to tell people that you forced to do that, "Well, if you try to challenge this, we will throw this agreement out and we will go after you, and you will face more severe consequences if you do."

That is not the role of a Government agency. The role of a Government agency is to protect the interests of the public, and it seems to me that you have politicized this process in a way that has severely damaged the credibility of the Environmental Protection Agency.

Mr. ROBERTSON. Well, Mr. Chairman, I don't believe that we circumvented the TRAC process. On azinphos methyl, as Dr. Carlson has pointed out, it had been fully through the first five stages of the process. The sixth stage is for EPA working in consultation

with USDA to decide what risk mitigation measures we were prepared to take, and we had been able to have those conversations with USDA.

Mr. GOODLATTE. Mr. Rominger, do you support the action taken by EPA?

Mr. ROMINGER. We did have an opportunity to review both the risk assessment and the regulatory action that was proposed by EPA, and I think if we had had more time, we probably would have done some more work with our——

Mr. GOODLATTE. Why didn't you have more time?

Mr. ROMINGER. We agreed that it did seem prudent to take some risk reduction measures on these two chemicals——

Mr. GOODLATTE. Well, wait a minute, you can't have it both ways. You were about to say if you had had more time, you might have been able to produce more documentation to satisfy everybody in this process, and at the same time you are saying you are agreeing that some action needed to be taken. You can't have it both ways.

Mr. ROMINGER. No, I said we would have involved land grant universities and continued discussion of the mitigation measures——

Mr. GOODLATTE. To get more input on the——

Mr. ROMINGER. It could have provided some additional input, but we felt, given what we knew about the materials, that it was prudent to take some risk reduction actions now. I think we have to look at the future needs as well, and the cumulative risk, because even though we might be comfortable with the risk presented by any one chemical, we have keep in mind that we are going to be looking at the cumulative risk of all the organophosphates. So, we thought it was prudent to take some action.

Mr. GOODLATTE. The gentleman from Texas, Mr. Stenholm.

Mr. STENHOLM. Mr. Chairman, if I ask questions that have already been asked, I would appreciate being interrupted and saying we don't need to go down that track again.

Mr. GOODLATTE. Well, the answers haven't been too satisfactory, so most of them are probably worth asking again.

Mr. STENHOLM. Dr. Carlson, do you think the TRAC process was followed in EPA's decisions that were announced yesterday? If not, would you please explain?

Mr. CARLSON. We thought it was followed through the fifth phase, but as we got to the end of the fifth phase here, it was rather hurried, and we got into a risk mitigation discussion where we thought there could have been more time taken to get more inputs from the grower communities, et cetera, which we understood was to occur in phase 6 of the pilot process, as outlined in the TRAC.

Mr. STENHOLM. So the answer was that the TRAC process was not followed because phase 6 was not allowed to go forward as was agreed to.

Mr. CARLSON. Yes, sir.

Mr. STENHOLM. Mr. Robertson and Mr. Rominger, would you please tell us about the alternatives that are available to be found in methyl parathion, and whether they are as efficacious and cost-effective as the products that we now have?

Mr. ROMINGER. I would ask Keith Pitts, my expert on that subject, to answer that.

Mr. PITTS. As we went through the process with these two chemicals, we were on the phone quite a bit with commodity groups both here in DC and out in the field with Extension Land Grant experts. We are comfortable that with regard to methyl parathion, that adequate alternatives do exist. In the case of orchard crops, azinphos methyl will be an important alternative, as well as phosmet and corperaphos, and while those risk assessments are not completely done for those other two OPs, our understanding in discussions with EPA is that they are generally looking good. Methyl parathion is one of the tougher chemicals we have had to deal with in this process. There also nice and new insect growth regulators which will replace methyl parathion uses. In regard to azinphos methyl, our discussions and our knowledge of that particular chemical and its use in IPM systems, we do realize that in some cases there are not adequate alternatives, and we think that the agreement reached there reflects the fact that there are not adequate alternatives available in some instances. We spent a lot of time in particular working with apples, peaches and pears in that regard.

In toto, we do feel like the end product of these two agreements is something that agriculture can work within comfortably. We, of course, never want to give up any tool, but do realize that the situation with risk assessments did require some mitigation.

Mr. STENHOLM. That is one of the troubling aspects of the action that was taken yesterday, because we kind of agreed on transition time. Where there is an imminent health hazard, there is no argument whatsoever about any actions taken, and that should be reported over and over and over again. But it is important to recognize transition time because, if you do take a tool away from our producers, those who are bound and determined that that is what they want to do, starting with these two, but they would take away all the tools of technology—some few among them, not all—and that is an unfair categorization to brand them all that way, but the ones that seem to get the news media attention are in that category. Transition time is extremely important to this.

Dr. Carlson, it is my understanding that the 99.9 policy is set to be finalized by EPA in September. It is also my understanding that EPA used 99.9 in guthion's risk assessment. Is it true that at the 99.8 percent confidence level, the risk would be measured at 100 percent of the risk cup rather than at 130 percent of the risk cup at 99.9 percent? And, Mr. Robertson, I would also like to hear your comments on that issue.

Mr. CARLSON. Yes, that is true. That was indicated in the technical briefing document for azinphos methyl.

Mr. ROBERTSON. Yes, Mr. Stenholm, the 99.9 is an issue in regard to azinphos methyl. We have clearly stated throughout the TRAC process that we have science policies in place in order to make decisions. We put those science policies out for notice and comment, and we expect that notice and comment period to improve our science policies, but these science policies have been peer reviewed, external peer review. We have taken them to the SAP. So we feel like we have a good basis for action where we think action is appropriate.

The action as regards azinphos methyl is—I think it is important to remember that we are not getting rid of most of the uses of azinphos methyl. What we are doing is cutting back on the tolerance here. azinphos methyl will still be available as a tool for most of the important crops that have used it. And we tried to tailor the risk reduction strategies carefully to the risk that we felt was presented.

Mr. STENHOLM. We have tried now for several weeks to get an answer to this question—I know there won't be a better one today—and that is, when we had a process set up that was clearly spelled out with six steps, that would have taken into consideration what you yourself have just stated—and I understand is the policy of EPA—but what you manage now, you are going to get sued by the folks on the other side, you are going to get sued by the folks on the other side of the other side, which normally——

Mr. ROBERTSON. We already have been in both cases, I think, Mr. Stenholm.

Mr. STENHOLM. Well, there are probably going to be some others.

Mr. ROBERTSON. No doubt.

Mr. STENHOLM. But, normally, when you get into this process in which you have folks on both sides mad, you have done something good. But in this case, honestly, it seems that we have not, because one of the things that concerns me most about the action is the fact that we had a process set up that someone decided needed to be shortcircuited for some reason other than that which had been agreed to and other than, which I have noted, that EPA had been following prior to the decision to circumvent it. And that is the problem because, if we have that kind of a lack of confidence in the process, it is going to be difficult to keep from shooting the messenger every time the messenger comes forward. And we can't put the genie back in the jug now.

I guess my final—no, I don't think I will ask that question. Thank you, Mr. Chairman, I appreciate your indulgence.

Mr. GOODLATTE. Thank you. The gentleman from Illinois, Mr. Ewing.

Mr. EWING. To Mr. Pitts, it is good to see you on that side of the table.

Mr. PITTS. Wish I could say the same. [Laughter.]

Mr. EWING. I wondered if it was as comfortable.

Methyl parathion that you have eliminated the use of is used a lot by the nursery industry. What is the major fallback for that industry? What other chemicals would they use?

Mr. PITTS. I am not sure on that regard, we will have to get back to you. I think there is some question about whether it is on nursery stock, as far as methyl parathion goes.

Mr. EWING. Mr. Vroom, do you know?

Mr. VROOM. My understanding is that there was a wide range of uses, some of which were obsolete but some of which we have just been hearing from some of the varied grower interest, both in terms of ornamentals as well as seedling stock for the pulp and paper industry, were more important than the industry registrants had realized, and there may not be any replacements for some of the uses. It is an example, in fact, of sort of the fallout, impractical fallout, of the speed with which these two decisions were finalized

here in recent weeks, that there hasn't been time to do an exhaustive kind of check to see will some grower interest fall between the cracks. And that is true with regard to food as well as nonfood uses.

Mr. EWING. Does anybody on the panel know?

Mr. PITTS. Congressman Ewing, I think one of the issues may be azinphos methyl, which there were some restrictions on that placed, and one thing that we did in the process is we did understand that this issue with southeastern seedlings was impacted. Earlier in the negotiations, we didn't realize that. We did correct that particular issue. There is a quarantine use of azinphos methyl that the nursery industry also deems critical, and we agree with them. We did not know about that prior to Monday. We did find out about it today, and we have been talking with EPA about ensuring that that use is reinstated. But that is azinphos methyl.

Mr. EWING. Well, it is my understanding that methyl bromide may be one of the alternative chemicals to be used. I don't think that is where we want to go. And I apologize to the chairman for being late, I was in the Banking Conference Committee, and would rather have been here because I really believe that when you look at how the legislation, the FQPA, was passed overwhelmingly by the House, we never intended the type of administration we are getting, and neither did the citizens of this country. I think it is just about time that the EPA and you at the USDA start working with the American people and the farmers, and those who need your help, and get your head out of the sand. It is really disturbing and really causes a lot of consternation back home. Thank you, Mr. Chairman.

Mr. GOODLATTE. Thank you. The gentleman from California.

Mr. POMBO. Mr. Robertson, you said that one of the concerns or problems you had with my legislation was the delay, the endless delay, and you felt that that would be a problem. And I think that what we are looking at here, from all the testimony that we have received from you, from USDA, from the manufacturers of one of these, is that the science wasn't complete and yet we made a decision. And I don't really understand—in your statement a few minutes ago, you said that we were expecting more data in, we were in a comment period, and we were expecting that to give us more information. You said that the process was out to be peer reviewed, and you were expecting information in on that.

This is exactly why I introduced the legislation, because of just that, what you just said. All of this is happening. We have all this new information coming in. We are doing some peer review finally. We are doing some peer review—we are doing all this stuff, and yet we had a huge press conference and a very public thing that put doubt in people's minds about the safety of our food supply, and you haven't even done the science yet. You are not done doing the science, and you are making decisions. And you are not just making decisions, you are doing it in a way to make sure that it is as public and as scary and as horrible as you possibly can. That is why I believe the legislation is necessary. Why are you afraid of doing the science?

Mr. ROBERTSON. We are not afraid of doing the science, Mr. Pombo. What I said was we have science policies in place that have

been externally peer reviewed. We are putting them through a public notice and comment process, but if we were not to act on the science policies that we have in place, we wouldn't have been able to make any of the registration decisions that we have made in the 3 years since the passage of FQPA, that have allowed us to register 47 safer new pesticides over the past 3 years.

Mr. POMBO. Are you saying that in this particular process, that you have followed all of the policies and all of the science was complete and you have the information in front of you to make an informed decision?

Mr. ROBERTSON. I am saying that we have the information in front of us to make an informed decision on these two substances, yes.

Mr. POMBO. And you followed all of the policies, and if someone says that all of the policies that were outlined in the different documents, in the legislation and through the TRAC process, if somebody said that you did not follow all of those policies, they are not testifying truthfully before this committee?

Mr. ROBERTSON. We followed the interim, if you will, science policies that we have in place, those science policies that have been peer reviewed, in making the decisions on azinphos methyl and methyl parathion.

Mr. POMBO. So you are saying that they are not testifying truthfully when they say that the policies have not been followed?

Mr. ROBERTSON. I am giving you my testimony, Mr. Pombo, I am not commenting on the testimony of others.

Mr. POMBO. Well, somebody is not giving accurate testimony because I have been told repeatedly that the process was not followed, and that all of the policies were not completed.

Mr. ROBERTSON. You may be referring to the TRAC process, the six-stage process of the TRAC process, Mr. Pombo, which a number of both members of the subcommittee and panel members have commented on. As I have said before, the six-step process for azinphos methyl was followed. We have stated publicly, repeatedly, throughout the TRAC process, that where the data clearly indicated that action was necessary, we would not be tied to the TRAC process in a way that would prevent action where action was appropriate. And on methyl parathion, where we were looking at risks 881 percent of the risk cup, we thought that action was appropriate in this instance. And we did announce the cancellation agreements and risk reduction measures regarding methyl parathion at the same time of the technical briefing, which is at the beginning of phase 5. Frankly, I think that that may be a better thing to do than simply to have put a refined risk assessment out there that says we are at 881 percent of the risk cup, and then doesn't provide any sort of indication to the American people what that means or what we are going to do.

What we stated is we are going to take action to protect the children of America, by taking off the uses on fruits and most vegetables, the things that make up the biggest part of kids' diets. It accounts for 90 percent of the risk, but it accounts for only 10 percent of the use of methyl parathion. So, I think that is a more appropriate way for us to act, and we have said throughout the TRAC process that when there were individual substances like this,

where the magnitude of the risk suggested that we needed to take action, that we would take action, and that is what this has been about.

Mr. POMBO. Unfortunately, as I have watched this process move forward, I have also watched the huge, inflated percentages of the risk cup change dramatically as you move through the process. And when you do not complete the science, you end up releasing information exactly as you just did, saying that the 880 percent of the risk cup was filled, even though you haven't completed the science and the data is not complete, and all of the information has not been turned into you, and yet you are testifying here today and saying in public that this is an extremely dangerous chemical, that it is 880 percent of the risk cup, based upon faulty assumptions that have been made because you have not done all of the science.

Mr. ROBERTSON. We have done the science to be confident of the level of the risk presented by methyl parathion. We are, indeed, continuing to collect public comment on our science policies, but we do not believe that the comment on the science policies that are still pending will affect in a significant way the level of risk for methyl parathion.

Mr. POMBO. I know my time has expired, Mr. Chairman, but I think that points out exactly what the problem is. You have policies that are being challenged because of faulty assumptions, because there are many people in the scientific community who feel that your policies are not scientifically accurate because of the assumptions that are being made within that, and you have the opinion that you can proceed along these lines because of faulty assumptions. And that is a big part of the problem.

I think we can all agree that we want good science, and we can all agree that we want this to be accurate when it comes out. Why these decisions were made, I can't explain, but I am very, very concerned not just in what happened yesterday, but in the testimony we are hearing today. I think it just re-emphasizes the need for the legislation, to hear the things that you are testifying to, and the assumptions that you are making and the statements that you are making here today. I think it just emboldens the need for the legislation. I thank the chairman for the time.

Mr. GOODLATTE. Thank you, Mr. Pombo. The gentleman from Texas.

Mr. STENHOLM. I think we have belabored the point and our differences enough. I would be remiss if I didn't acknowledge the fact that the three of you at the table have been very good to work with over the past year in all sides of the question.

Mr. Robertson, this being your, I believe, last opportunity to come before this esteemed committee today—I would want to say to all three of you—it is a difficult issue that we have been dealing with.

This decision was made above your pay grades, and I understand that. We understand how these things go. But let me say on a positive note also, and end it with a question. We have already seen some very irresponsible and, frankly, untruthful statements in the press being made by some interpreting this decision in their way. And yesterday EPA did a good job trying to ensure consumers that our food supply is still safe.

Is EPA committed to continue to make these statements as often as is necessary to combat these statements by these individuals in the press?

Mr. ROBERTSON. Absolutely, Mr. Stenholm. I think you will probably see it when Administrator Browner is on Jim Lehrer this evening. We will certainly repeat it as often as we deal with this issue. As Administrator Browner has said, as Secretary Rominger has said, the food supply is safe. We think we can do better. And that is what this is about, doing better.

Mr. STENHOLM. A final question. Mr. Lovelady, I would like to ask how you felt about the TRAC process a year ago, and how you feel about it today?

Mr. LOVELADY. Mr. Stenholm, a year ago this process was very new. I think we all had hopes that this would answer a lot of questions, and that we would develop a good science based policy. And even as recent as April when I testified before this committee—and I remember your testimony, too, that you were pleasantly surprised at how well things were going—and I felt the same way and testified as such.

I don't feel as good today. I feel like that we, on the TRAC, or some of us on the TRAC, have worked in good faith. And I would have felt better had the process worked completely through before we saw mitigation and cancellations like we saw yesterday. I feel like that the process has been compromised, and I hope—I hope—that it can be salvaged and that we can continue, but I don't feel as good as I did in April.

Mr. GOODLATTE. I want to thank all the members of the panel. I am very disturbed by yesterday's developments because it appears far more than coincidence that these two products were addressed on the particular date that they were addressed on, without having completed what I perceive to have been a good faith, agreed upon process to be followed, and I think it was shortcircuited, and I don't think we have heard the end of this issue, and I, for one, certainly want to try to get to the bottom of whether or not we can rely upon a sound system for determining what products should be on the market and what should not, or whether this system is going to be politicized and engender a good deal of distrust that is going to yield, I think, the removal of good products from the market and, as a result of that, we are going to ignore the other side of this process, which isn't just that, yes, we absolutely don't want unsafe products on the market, but we also want to make sure that everyone understands that these products are used for good purposes, to assure that we have an abundant, safe and affordable food supply. And if we don't follow a sound, trustworthy process to determine whether or not they are, we are going to lose the ability to continue to feed our ever growing population in a way that provides them with a very healthy diet.

So, I thank you all for your participation.

Mr. GOODLATTE. We are going to, in order to speed things along, combine the third and fourth panels. And at this time, I would like to invite all of those panelists forward.

I would first like to introduce Mr. Ralph Engel, president, Chemical Specialties Manufacturers Association, Washington, DC; Mr. Robert Rosenberg, director of governmental affairs for the National

Pest Control Association, in Dunn Loring, VA; Mr. E. Allen James, executive director, Responsible Industry for a Sound Environment, Washington, DC; Mr. Kevin Gardner, chairman of the American Farm Bureau Federation Young Farmer and Rancher Committee, from Cave City, KY.

In addition, we have with us Dr. George M. Gray, deputy director, Harvard Center for Risk Analysis, Harvard School of Public Health, Boston, MA; Dr. Jerome Goddard, medical entomologist, Mississippi Department of Health and clinical assistant professor of preventative medicine, University of Mississippi Medical School, Jackson, MS; Mr. George Wichterman, chairman of the Public Health Pesticide Working Group, of the American Mosquito Control Association and senior entomologist, Lee County Mosquito Control District, Fort Myers, FL.

I would like to welcome all of you to the hearing, and I would like to begin with Mr. Engel. As we indicated to the earlier, your written testimonies will be made a part of the record, and we welcome you to address the committee for 5 minutes.

STATEMENT OF RALPH ENGEL, PRESIDENT, CHEMICAL SPECIALTIES MANUFACTURERS ASSOCIATION

Mr. ENGEL. Thank you, Mr. Chairman and members of the subcommittee, and good afternoon. My name is Ralph Engel, and I am president of the Chemical Specialties Manufacturers Association, or CSMA.

CSMA has a membership of some 400 companies who manufacture, formulate, distribute and sell many types of consumer, industrial and institutional products, a significant number of which have pesticidal claims and are, therefore, subject to EPA jurisdiction pursuant to FIFRA.

In 1996, FQPA amended FIFRA, and among FQPA provisions were reforms to the antimicrobial registration process, including the establishment of performance goals and time lines for registration actions of antimicrobial pesticides.

Mr. Chairman, I am pleased to state that the EPA has made significant improvements in the overall registration of these products, maybe the most positive thing said about EPA today. Unfortunately, other sections of FQPA create greater concern and uncertainty in the system of registering pesticides for non-agricultural uses.

Our industry is concerned that EPA appears to be bent on implementation of the FQPA based on arbitrary deadlines that may lead to decisions based on faulty risk assumptions rather than good data and sound science, and we may have seen an example of that today.

If the provisions of FQPA are not carefully and properly implemented, many products that benefit and protect consumers could be lost.

CSMA defines non-agricultural pesticide products we represent as consumer protection and health benefit products because the term "pesticide", unfortunately, has a visceral, if not pejorative, connotation for the public. Moreover, the term "pesticide" focuses only on the function of the products, completely ignoring the many benefits derived from the use of these products.

Life today would be quite different without the use of pesticides—disease would likely be widespread, food would be scarce, and certain areas of the country would be uninhabitable, overrun by pests.

There are significant benefits that can be achieved by the use of non-agricultural pesticide products. For example, disinfectant products are used by millions of people every day to help prevent the spread of germs, and to eliminate the mold that can also cause severe health problems.

Pet products are vital to keep both families and pets healthy and comfortable by protecting them from disease-carrying fleas and ticks. Insect repellents are also critical in protecting the public against tick and mosquito borne diseases, such as Lyme Disease and encephalitis, that have become rapidly emerging public health threats.

Insect and rodent control products protect against the transmission of disease by these pests. Recent research has found that cockroach allergens and house dust mites are leading triggers of asthma among children in the inner-city.

We know that consumers understand and appreciate the benefit of our products. A California survey we commissioned late last year found that 78 percent of respondents believe that society should do more to protect children from insects and rodents; 47 percent believe that the children are becoming sick due to contact with insects and rodents; in addition, 64 percent affirm that household pesticide products are crucial for keeping their homes free from insects and rodents. These public health benefits should be fully considered and heavily weighted during the regulatory and decision-making implementation of FQPA.

Among the material that was distributed to you was a book called Dangerous Pests. I suggest that you take a look at it, it is quite enlightening.

Science-based implementation of FQPA requires both time and a process that will accommodate the data, and assessment methods that industry is working to develop in cooperation with EPA. The Tolerance Reassessment Advisory Committee, TRAC, was formed by EPA and the Department of Agriculture to address the implementation of FQPA. CSMA is a member of the committee. TRAC has focused on the development of nine science policy issues, including two that are of extreme importance to CSMA, residential exposure and aggregate risk.

First, residential exposure. CSMA has a number of concerns with the EPA draft Standard Operating Procedures for residential exposure assessment. These SOPs do not currently consider publicly available scientific literature. This literature would most certainly displace some of the overly conservative default assumptions. EPA should revise these SOPs to replace best judgement assumptions with available data as soon as possible. Furthermore, EPA should use the revised SOPs only as a first-tier screen to determine whether more data and/or a higher tier assessment is needed.

Turning to aggregate exposure. Aggregate exposure to a pesticide can occur by multiple routes from multiple sources. EPA has developed models for estimating exposures, but these models are based on unrealistic assumptions that overestimate the actual exposure.

Thus, when aggregated assumptions for a given pesticide are too conservative, an exaggerated exposure scenario may result. If final decisions are made prior to availability of data, valuable non-agricultural pesticide products may be lost. That is why it is important to base decisions on good science and good data.

In addition, we are concerned about the allocation of content in the so-called "risk cup" and the need to preserve residential pesticide uses which maybe forced out of the cup by other risk drivers. In order to respond to FQPA issues related to non-agricultural pesticides, CSMA has formed two joint ventures. The first is the Indoor Residential Exposure Joint Venture. This is a group of companies that manufacture and formulate pesticide products for residential and commercial markets. This joint venture has currently undertaken a program consisting of two comprehensive projects, a label data entry system and an unprecedented major national consumer use survey. These components will be used in the creation of a database relating to product use that can be incorporated in modeling tools that are being designed to create exposure and risk assessments for all pesticide products.

The second joint venture is the Antimicrobial Exposure Joint Venture. It also operates under CSMA auspices and consists of manufacturers and formulators of antimicrobial pesticides. This joint venture is currently collecting information and developing a viable program to address necessary data requirements.

In conclusion, the implementation of FQPA must be based on good data. Should the FQPA be administered on the basis of faulty risk assumptions rather than sound data, the likelihood is that non-agricultural pesticides or consumer protection and health benefit products that are vital to consumer health and quality of life may be lost.

We believe it is more important for the agency to make the right decisions based on good data and sound science than it is to meet arbitrary deadlines. We urge the subcommittee to advise EPA to allow sufficient time to: (1) gather residential exposure and aggregate risk data; (2) permit data generation under appropriate study guidelines and protocols; and (3) and most importantly, to establish a process to ensure that non-agricultural pesticides are not forced from the risk cup by other risk drivers.

On behalf of CSMA, I appreciate the opportunity to appear today to discuss the benefits of non-agricultural pesticides and implementation of them related to FQPA. Thank you very much.

[The prepared statement of Mr. Engel appears at the conclusion of the hearing.]

Mr. EWING [presiding]. Thank you, Mr. Engel. I am now going to Mr. Gray, and would remind the panel that Mr. Engel had special dispensation for a little more time. We would like to stay with the 5-minute rule, if possible, because of the number of witnesses and the hour. Mr. Gray.

STATEMENT OF GEORGE M. GRAY, DEPUTY DIRECTOR, HARVARD CENTER FOR RISK ANALYSIS, HARVARD SCHOOL OF PUBLIC HEALTH

Mr. GRAY. Thank you, Mr. Chairman and members of the committee. My name is George Gray. I am a lecturer in risk analysis

at the Harvard School of Public Health, and the director of the Program on Food Safety and Agriculture at the Harvard Center for Risk Analysis.

Before I talk about the public health aspects of implementation of FQPA, I do want to put Mr. Pombo's mind to rest about feeding apples to kids. I am a father with two small kids, a wonderful wife. I also happen to be the one in the family who does the grocery shopping. I am a toxicologist, so I know the science; I am a risk analyst, so I know the exposure assessment and the risk. I don't buy organic. I buy as many fresh fruits and vegetables as I can, and feed them to my kids—as many as they will eat. We have heard already about the trouble getting kids to eat as much fruit and vegetables as they will.

My point is, I don't have concerns about the safety of the food supply. What I have concerns about are the public health aspects of the way in which we are implementing the FQPA.

Now, a fundamental tenet of public health that is borrowed from physicians is, "First, do no harm." That notion arises from the recognition that medical treatments and public health interventions have potential side effects. They have the unintended consequences that have the opportunity to reduce or even cancel out the benefit that we might get by taking action.

A well known example in public health is disinfection of drinking water to kill disease-causing microorganisms. All of our technologies for addressing those micro-organisms have potential side effects, and we work very hard—we are aware of them and we work hard to minimize side effects while still treating that much larger risk to get the benefit of reducing disease-causing microorganisms.

I am here to tell you today that current implementation of the FQPA is not paying enough attention to the public health side effects of regulatory actions. Because of a narrow focus and lack of consideration of foreseeable consequences, we cannot be sure that implementation of the FQPA will provide significant public health benefits, and it may even do harm.

For example, it is clear that banning of a pesticide does not cause the target pest to disappear, and we have already talked about that in this hearing. Something else or another pest management practice will be used to protect the crop. Now, we have talked about the fact that we need efficacious alternatives, but don't forget, any alternative pesticide will have its own toxicity profile and its own associated potential for risk.

You might be surprised to know that the decisions about pesticides for some of our crops don't evaluate the risks of the materials that will take their place. It is clear that these alternatives will reduce the amount of risk reduction that we might get, and might even cause the risk to increase if they are less effective, if they require more applications, or if they are more toxic.

Substitute pesticides are only one of these countervailing risks. There are risks that may occur to public health or crop reduction if pest control is weakened in the absence of a particular pesticide. There are public health implications of the economic disruptions that a change in pesticide availability can cause. Evaluating the degree to which countervailing risks may diminish, or even out-

weigh, the target risk of a regulatory action is critical to ensuring sound implementation of FQPA.

I do believe that Congress thought about this when the FQPA was under consideration. There is a clause in the FQPA, the substantial disruption clause, that recognizes changes in the availability of a pesticide may have significant public health risks of its own.

The committee report clearly identifies the countervailing risks of alternative pest control methods, changes in yields of crops, and consequent effects on consumer diets and nutrition through changes in food availability or price. This is extremely wise and farsighted action by Congress, and although the committee report suggests that this will happen only occasionally, I think it has to be an integral part of any decision under FQPA.

Very briefly, I want to tell you about some work I am doing with a colleague, in which we are evaluating the risk/risk tradeoffs that would be involved with a ban on the organophosphate and carbamate pesticides. This is work that is funded by the American Farm Bureau Federation.

Our study hasn't yet been peer reviewed, but there are a couple of comments that I can tell you. First, it is very difficult to estimate any benefit to public health that would occur from a ban on OPs and carbamates. Second, countervailing risks do exist and will offset many of the positive effects that a ban might have and might even make things worse. I believe all of these countervailing risks are potentially covered by FQPA, but they are not part of the current implementation. I hope that we will think about countervailing risk to get the most public health benefit in the future. Thank you.

[The prepared statement of Mr. Gray appears at the conclusion of the hearing.]

Mr. GOODLATTE [presiding]. Thank you, Mr. Gray, for that very helpful testimony. Mr. Goddard, welcome.

STATEMENT OF JEROME GODDARD, MEDICAL ENTOMOLOGIST, MISSISSIPPI DEPARTMENT OF HEALTH

Mr. GODDARD. Thank you, Mr. Chairman and members of the subcommittee. I speak to you today from the perspective of a public health entomologist. I am responsible for insect calls for transmitted diseases in the State of Mississippi. Pesticides are environmental medicines—that is not my term, but I like it—to help us correct imbalances in nature, and there are imbalances in nature. The world is not like that portrayed by Disney, it is a struggle for survival. Things are catching, killing and eating each other. Diseases and parasites abound among both plant and animal life.

It is easy for us in the United States to be somewhat deceived and not see the struggle for survival. People in million-dollar homes and who buy their food in supermarkets have not seen the terrible scourges that insects and insect-carried diseases can bring upon humans. All you have got to do is go to the tropics and you will quickly see that almost every disease is caused by or carried by an insect. And with widespread frequent international travel, these disease can be easily introduced in the United States.

About 2 years ago there was a man who had been on an eco-vacation in Brazil. Came back to some small town in Tennessee, came down with a fever, walked into a small town clinic and said, "I have a fever." They said, "Yeah, you have a virus." He had a virus all right, he had Yellow Fever and died.

Dengue Fever rages in the Caribbean and each year comes dangerously close to the United States. In 1995, there were cases in the Renosa, TX area.

Talking about imbalances in nature, I personally have seen mosquito landing counts exceeding 200 per minute. All life is totally unbearable in places like that. I personally have collected ticks where we collected over 5,000 ticks in a 30-minute sample. It would be absolutely impossible to stand there, sleep there, picnic there, work on a car there, do anything.

I went to an Emerging Infectious Disease Conference at the CDC a couple of years ago, and there are a whole host of new and emerging diseases. This is the new buzz word, "emerging." The program for this conference was as thick as a Sears catalogue, so you could just pick any disease you wanted to die by, but a large portion of those diseases were carried by insects.

We need pesticides. And in my view, we need as many different formulations and registered uses as possible. You never know when resistance may develop to a particular pesticide, making that pesticide of no effect. Just like in medicine where doctors need many different antibiotics to fight resistant germs, we need many different pesticides to fight a whole host of insect pests, some of which are resistant to pesticides.

I urge you to use your oversight over the EPA and their implementation of the FQPA to assure that these products remain available to us. You never know when we might desperately need them. Thank you, sir.

[The prepared statement of Mr. Goddard appears at the conclusion of the hearing.]

Mr. GOODLATTE. Thank you very much, Mr. Goddard. Mr. Wichterman, welcome to the committee.

STATEMENT OF GEORGE WICHTERMAN, CHAIRMAN, PUBLIC HEALTH PESTICIDE WORKING GROUP, AMERICAN MOSQUITO CONTROL ASSOCIATION

Mr. WICHTERMAN. Thank you, sir. I am George Wichterman, chairman of the Public Health Pesticide Working Group for the American Mosquito Control Association, and senior entomologist with the Lee County Mosquito Control District in Fort Myers, FL. I am also a member of the FQPA Tolerance Reassessment Advisory Committee, representing public health vector control. Accompanying me today are Joseph Kertesz, AMCA Mid-Atlantic Regional Director of Hampton, VA, and past president of the Virginia Mosquito Control Association, and Ms. Judy Hanson, past president of the AMCA and current president of the New Jersey Mosquito Control Association. We would like to thank Chairman Goodlatte for his leadership in holding these important hearings on the implementation of the FQPA, especially focusing on the importance of public health pesticides in preserving and protecting our Nation's public health.

AMCA is a nonprofit international association, involved in supporting mosquito and other vector control. As a member of the public health community, I cannot fairly report that we have made significant progress in implementing the public health provisions of the 1996 act. Specifically, HHS has not established a home for this key program. Moreover, HHS has not sought the money needed to conduct studies to maintain the public health pesticides needed to fight vector-borne disease such as encephalitis which is on the upswing. Without this arsenal, we are at risk. The insects become immune.

Most of the multinational companies develop pesticides for agricultural use, since that is where the profit is. Mosquito control programs use comparatively small amounts of pesticides. The manufacturers of pesticides historically have been reluctant to develop the aquatic toxicity and fate data required to maintain product registration of mosquitocides. Without this data, the EPA will not reregister these mosquitocides. If we do not have a variety of pesticides to use, we face the prospects of mosquitoes developing resistance.

One FQPA objective is to require EPA, in consultation with HHS, to consider the unique needs and benefits of public health pesticides and for HHS to conduct the testing needed to support the registration.

Congress envisioned HHS serving a critical role in the preservation of public health pesticides. HHS, unfortunately, has not stepped up to the task. With mosquito-borne diseases increasing, placing at risk children and the elderly—an ironic development, especially since FQPA was born out of concern for children's health.

I urge this committee and Congress to remind the Secretary of HHS of the Department's role under this law. FQPA specified several new regulatory obligations for the EPA and HHS, requiring a new regulatory liaison between the two agencies. Despite considerable effort, however, the two agencies have still not determined how this cooperative arrangement will be handled.

We would urge both agencies to finalize these agreements so that their regulatory responsibilities are clear. EPA has taken the initiative in this regard and appointed a Public Health Coordinator to address these issues, however, HHS has not. Rather, HHS views its responsibilities under this Act as an unfunded mandate.

For more than 2 years, the EPA, in consultation with HHS and the USDA, has worked on the publication of a public health pest list. We urge the EPA to expedite the list publication with a 90-day comment period so that all public health officials could comment on it.

Public health pesticides provide many benefits, such as preventing the spread of infectious diseases, improving the quality of our lives, and protecting our most vulnerable group—our children and senior citizens. As a resident of southwest Florida, I know that only too well.

One of the most important provisions of the FQPA called for the establishment of a Public Health Pesticide Data Collection Program. The development of this data is essential to maintain a viable mix of mosquito control products. Under section 4 of the act, appropriations of $12 million were authorized for fiscal year 1997 and

future years. HHS has not requested this money or developed a program for this data, nor is it clear that such a spending request will be made in fiscal year 2001. It is important that this program be started as quickly as possible, since there are three public health pesticide products being reviewed by EPA, and the agency has identified data gaps for each.

It has been determined by individuals within the agencies that $7 million would be needed to satisfy these data requirements for re-registration. Unfortunately, HHS has been unable not only to establish a home for this program, but it also has not provided the money to support these orphan public health use pesticide products.

For 37 years, the USDA has been successful doing this type of program of testing. Many public health products will disappear if money for the program is not approved. These products which are low-volume, low-profit, will be lost in registration and re-registration due to economic reasons. Simply put, the cost of generating the necessary data to continue these registrations far exceeds the return on the sale of the products.

We respectfully urge the EPA, HHS and the Clinton administration to work together to implement the Public Health Pesticide Data Collection Program so that it can begin by the start of fiscal year 2001. Consequently, we at AMCA believe it is important to fully implement the public health provisions of FQPA. This is what we need to do: provide the funding, establish a program within HHS, complete the pest list, establish the benefits of public health pesticides, and establish the Public Health Pesticide Data Collection Program. Thank you, Mr. Chairman.

[The prepared statement of Mr. Wichterman appears at the conclusion of the hearing.]

Mr. GOODLATTE. Thank you. Mr. Rosenberg, we welcome you and are delighted to have your testimony.

STATEMENT OF ROBERT M. ROSENBERG, DIRECTOR, GOVERNMENTAL AFFAIRS, NATIONAL PEST CONTROL ASSOCIATION

Mr. ROSENBERG. Thank you, Mr. Chairman. Considering the time of night, I am kind of guessing you would prefer I keep this short, so I am going to try to summarize.

Mr. GOODLATTE. It will all be in the record.

Mr. ROSENBERG. I appreciate that. What I mostly appreciate is the fact that you all are paying some attention and shedding some light today on an issue that has been all but ignored, namely, public health, residential, non-agricultural use of pesticides.

The folks that I represent are pest control operators. These are folks like Orkin and Terminix, and 5,000 small companies that do residential, commercial, institutional, industrial pest control, who rely on these products to deal with termites and cockroaches and flies and ants and a whole host of diseases that I suspect everybody is very familiar with.

In a nutshell, the problem that we have with the way in which EPA is implementing FQPA amounts to this: the law says that EPA must conduct this thing called aggregate risk assessments. They are going to have to add up dietary exposure, drinking water

exposure, and residential exposure. The law never required that before. We are perfectly happy with aggregate exposure assessments.

The problem in a nutshell is this: Now that there is going to be this single risk cup adding up all these different sources of exposure, prior to the passage of FQPA, number one, there were no data requirements for residential exposure products. They did not exist. There was no statutory requirement.

Number two, EPA, since the passage of FQPA, since 1996, has not exercised its data call-in authority, the authority which was expanded by FQPA.

Number three, USDA has made, I think, almost an heroic effort to try to generate data where there were gaps in the data that EPA had to make dietary exposure assessments. There is no USDA out there. There is no Federal agency out there generating data to support the other uses.

Number four, EPA itself has not collected that data.

Number five, industry is in the process of trying to—we all woke up one day and said, "Geez, we are all going to need data"—we are trying to collect data. We are not having an easy time finding out what data it is that EPA will use and what format they will accept it in.

The TRAC process which we have heard so much about here today maybe has worked well. The tone of today's discussion was if the EPA had simply abided by the TRAC process, that everything would have been OK. For those of us who aren't in the agricultural business, those of us who manufacture or use non-agricultural products, there has been no TRAC process. This subject has been ignored. It has not been discussed, and there is no TRAC for non-agricultural, folks. The bottom line is, there is no data. There is no science.

Here is what EPA itself says. This was in the Federal Register notice which they published, the one Federal Register notice on residential exposure. Quoting EPA, "Highly specific residential exposure data are generally lacking, and there is not wide understanding and acceptance of existing models and assumptions." There is no data. There is no science. But here is what they have also said. They said, "We don't have data, we haven't figured out the science, but what we are going to do instead is this, we are going to use default assumptions, worse case scenarios", that everybody, including EPA, has acknowledged will greatly exaggerate the risk associated with residential exposure.

Congress understood this. When you all passed this, the first time around you said that EPA ought to take into account other routes of exposure like residential exposure, if there is reliable information. That is the language of the law. Congress understood it. EPA ought to understand it.

Here is what is going to happen. When they get done doing residential exposure assessments, risks from residential exposure will be so high that one of two things is going to happen, either wee are going to lose what to us are valuable, irreplaceable products, or if a manufacturer chooses to retain a use in our market and it is going to eat up such large chunks of space in the risk cup that there will be no uses available for farmers of that product.

Mr. Chairman, we thank you very much. We don't think EPA is ready to make these decisions if they are intent on moving forward without data and without science. We urge you to exercise your prerogative to enact legislation to slow them down and stop this travesty. I thank you.

[The prepared statement of Mr. Rosenberg appears at the conclusion of the hearing.]

Mr. GOODLATTE. Thank you.

Mr. James.

STATEMENT OF E. ALLEN JAMES, EXECUTIVE DIRECTOR, RESPONSIBLE INDUSTRY FOR A SOUND ENVIRONMENT

Mr. JAMES. Thank you very much, Mr. Chairman. I am Allen James, the executive director of RISE, which means Responsible Industry for a Sound Environment. We represent over 150 companies and other associations that manufacture and produce pesticides used in the urban environment, generally, all non-agricultural pesticides, with the likely exception of antimicrobials. We produce those pesticides used in public health, general pest control, lawn care, golf courses, other turf areas, vegetation management and aquatic pesticides. I am going to reduce my comments to very short remarks because both Dr. Engel and Dr. Rosenberg have so fully covered my testimony for me that it is not necessary that I cover it all again. However, I wanted to bring to your attention some information from one of our member trade associations, the American Nursery and Landscape Association, regarding a topic that was brought to your attention earlier today, and really didn't get the consideration that it deserved by EPA and USDA.

When they were talking about azinphos methyl, they acknowledged that there were some uses that USDA had overlooked for nursery and ornamental products for this particular chemical. The fact of the matter is that this particular chemical, azinphos methyl, is very critical in certain ornamental nursery production in two western States, Oregon and Washington.

I am reading from some written testimony that the American Nursery and Landscape Association has submitted to you, I am reading on their behalf.

> It is applied to fruiting and flowering apple and crabapple trees in parts of Oregon and Washington to control apple ermine moth.
>
> This use is mandated by State government quarantine restrictions designed to prevent accidental movement of this moth to major fruit-producing areas east of the Cascade Mountains and across the United States. Azinphos methyl is the only pesticide currently authorized by those States for treating apple and crabapple nursery stock for shipment during the growing season. Research efforts have not yet found efficacious alternatives.

Mr. Pitts indicated that this use was accidentally overlooked during their recent review of this product over, I guess, the weekend, when certain agreements were reached on the cancellation of this product. That use is now lost to these producers. Although he said, "Well, now that we have recognized that, we are going to ask the EPA to reinstate that use."

Then I must ask the question, what other use must now be lost to make up for that reinstated product use? I don't believe that would have happened if the full TRAC process had been followed

and full consultation had been undertaken, as was agreed by both USDA and EPA.

When the EPA rushes to judgment on these products and doesn't have a full database, and doesn't have full information about how these products are used, I fear—and the users of our products and the producers of our products share this concern—that more mistakes like this one will be made, and many other valuable uses will be at least temporarily overlooked.

But I wonder, more importantly, what would have happened today if a valuable public health product had been accidentally overlooked, or a valuable food use product had been canceled accidentally, and those uses no longer would be available. Those kinds of mistakes are serious mistakes.

Now, fortunately, in this case, it is a minor use out in Washington State and Oregon. I say that somewhat sarcastically because to those people who are producing those crops out there, those nursery ornamental crops out there, this was a rather serious mistake. Maybe this one will be corrected. I hope future ones don't occur because I hope that the Environmental Protection Agency and the USDA will more carefully implement FQPA as the Congress originally intended, and I hope that this committee will continue its valuable oversight and bring these kinds of mistakes to the public's attention. Thank you very much.

[The prepared statement of Mr. James appears at the conclusion of the hearing.]

Mr. POMBO [presiding]. Thank you, Mr. James. Just as a matter of clarification, you said that the use of that was necessitated by State law?

Mr. JAMES. Yes. This is a quarantine requirement by those two States to keep this moth from traveling through their products, the produced ornamental product, across State lines for sale, so they have to use this product to control this moth. There has not been an adequate product found to replace it. As I understand it, there is some possibility, as was mentioned earlier, of methyl bromide as a replacement product, which I don't think any of us believe should be, or probably is a very good replacement product.

This required use was overlooked in the process of evaluating this pesticide, this quarantine requirement. That is a serious omission.

Mr. POMBO. Thank you.

Mr. Gardner.

STATEMENT OF KEVIN GARDNER, CHAIRMAN, AMERICAN FARM BUREAU FEDERATION YOUNG FARMER AND RANCHER COMMITTEE

Mr. GARDNER. Thank you. Good morning, Mr. Chairman. I would like to thank you and the members of the subcommittee for holding this hearing and your continued work on this very important issue. I am Kevin Gardner, chairman of the American Farm Bureau Federation's Young Farmer and Rancher Committee. Together, with my wife Glenna and our four young children, we operate a corn, wheat, soybean, tobacco and alfalfa hay farm in Barren County, KY.

As a younger member of the farming community and an individual now only beginning to invest in the business of food production, I need to be assured that safe crop protection tools I depend on will be available to me when I need them. Starting out in farming is not an inexpensive undertaking. It involves, as you all know, a substantial amount of investment and risk. My creditors are relying on me to produce a product that has a value in order to return their investment.

I plan to farm for years to come. I also plan to support my family with a farm income, and supply consumers with safe and affordable product, but actions that were taken yesterday by Administrator Browner are reckless and have the potential to cause severe harm to many in agriculture.

As for children's safety, my wife and I shop at the same grocery stores and serve our children the same foods that ny member of the public would buy. Our food supply is safe and our ability to produce the safest, most abundant and affordable food on earth is unequaled. Our regulatory system is the most rigorous in the world, and yet that system, as it is currently being administered, threatens to do serious harm to family farms in this country, with no increase to consumer safety.

Yesterday's actions give me great concern because of the lack of any coherent objective or science-driven process. A year ago, Vice President Gore issued a memorandum with four basic principles to guide the implementation of FQPA. They are sound science, transparency, transition for agriculture, and public input. We welcome the attempt to establish a rational meaningful process. Until recently, it seemed to be succeeding in bringing some order to a very complex and difficult task. I believe the four principles are sound and based on common sense, but as a farmer they take on an additional meaning to me.

The first principle is sound science. I don't base decisions I make on my farm on default assumptions and shoddy science, and neither should the EPA. They are responsible for decisions that will affect me and my farm for years to come. Prior to FQPA, the focus was on dietary risk. After the FQPA, additional exposures must be considered, such as drinking water and residential exposure. These provisions make sense only if the agency uses real data and reliable information on which to base its assessments. To do otherwise doesn't make the regulatory system anymore protective of public health, only more difficult to navigate.

In light of the new requirements of FQPA, real data takes on even more importance. Worse case assumption about agricultural use when added to similar unrealistic assumptions from the structural pest control community and from drinking water models result in theoretical risk usually well above the safety standard, not real risk. The agricultural and the urban pest control community depend on each other and the agency to use real-world data, not default assumptions.

The second principle is transparency. As a grower, transparency to me means being closer to the consumer than ever before, and being able to tell that consumer how I raise a safe and affordable product.

Growers and the non-agricultural pesticide user community trusted the implementation process for the FQPA would be transparent and follow established administrative procedures for Federal rules and regulations. It hasn't.

Over a year and a half after the Vice President's memorandum and the first deadline now here, not a single science policy paper has bene finalized. How can the agency be making fair pesticide risk assessments at the same time they are still seeking public comment for this same process? Without these policies, can anyone possibly understand the process?

The third principle is transition and the availability of safe pest control products for farmers and other users. Transition on my farm is an ever-present event. I am constantly adopting new practices, but I base those on sound information, not guesswork and assumptions. I need to stay abreast of the latest technology and practices and then make reasonable decisions. The alternatives must be economical, safe and effective.

Farm Bureau supports corrective legislation to ensure fair and science-based implementation of FQPA. We want to thank all members of this committee for their help over the past 3 years and continuing assistance in achieving a fair and balanced implementation of FQPA.

In conclusion, our society derives significant benefits from the safe use of pesticides on farms and in the community at large. Last month, the U.S. Department of Health and Human Services released a new report documenting major improvements in Americans' health and citing, and I quote, the "consumption of five fruits and vegetables a day" is one of the major contributors.

Thank you for holding this important hearing and your attention to our concerns.

[The prepared statement of Mr. Gardner appears at the conclusion of the hearing.]

Mr. GOODLATTE [presiding]. Thank you, Mr. Gardner. I thank all of you for your testimony.

Dr. Gray, I have been very interested to find that the EPA charged with conducting risk assessment of these various products isn't assessing all of the risks, and your concept of risk versus risk I think is a very good one. The committee has heard about this concept in the form of unintended consequences of implementation during past FQPA hearings. I wonder if you could give us some examples of those unintended consequences of assumption based as opposed to science based implementation of the FQPA?

Mr. GRAY. Well, there are a number of them. And, in fact, I found very interesting the testimony earlier today about assumptions about exposure and the use of a 99.9 versus 99.8 versus a 97.5 percentile of a distribution exposure. From a technical point of view, the estimation of those particular numbers is fraught with uncertainty. It requires guesses, it requires assumptions, it requires unverified models. And yet we heard the incredible importance that it has for the survival of a product. That is an example in which defaults, models and assumptions can drive a particular conclusion that real data might well counteract. And I think that is what you heard about with the frustration that the public com-

ment on the use of those particular models hasn't even come back to the agency yet, and they are moving ahead to use them.

Mr. GOODLATTE. Now, do I understand correctly that if there is a consequence of a use of a product in another area that would prevent spread of disease or illness, that that isn't even taken into account? They are taking into account the direct ingestion of the product and the effect it has, but if you might get a mosquito infection or infection from some other consequence that this product could fight, it is not being taken into account in their risk assessment?

Mr. GRAY. Well, I mentioned in my testimony that, in fact, the bill is very farsighted about the potential for tradeoffs. I mentioned the substantial disruption clause that says we recognize that taking away pesticides can change diets because costs go up. We recognize that it can put farmers out of business, and those things have problems. It also recognized the public health benefits and something sort of, to me, I think of as the Aflatoxin clause that says some pesticides have risks, but they prevent a bigger risk. That thinking is in the FQPA. It is not being applied in the implementation. The opportunity is there, and it is just not being used.

Mr. GOODLATTE. Do you have any opinion as to why it is not being—surely they are aware of your and other challenges to their risk assessment procedures.

Mr. GRAY. That is a very good question. One thing I can tell you from doing it myself is, it is difficult. And another thing that it does is point out the shortcomings of some of the risk assessment methods that are currently used, including a lot of the defaults and assumptions, the 10X safety factor for children, all these kinds of things make these kinds of comparisons very difficult. It requires you to use the best science and the best data available in order to make the comparisons accurately. It is a little harder to do, but from my point of view, if we want to make sure we are doing a good job for public health, it is the only way to do it.

Mr. GOODLATTE. Thank you. Mr. Engel, you and your association should be commended for your leadership in a number of data development initiatives underway. Are you concerned that the current implementation process will not allow for the incorporation of such data into tolerance assessments?

Mr. ENGEL. We are concerned that the rush to judgment added to is not going to allow for data development, and proper data development takes time. And, yes, we are concerned.

Mr. GOODLATTE. Without these data, is it reasonable to assume that many uses may be endangered due to the faulty and arbitrary assumptions contrived by the EPA?

Mr. ENGEL. Yes. As a matter of fact, I will give an example. Currently, an indoor residential pesticide risk assessment has to do with carpeting. The agency makes the assumption that 50 percent of all pesticides in carpet are dislodged and can, indeed, come in contact with children or pets. But most recent measurements show that the dislodgeability of a pesticide residue in carpets is 1 to 5 percent, and that is measured. And, frankly, we also have found that the same percent relates to turf, not just to carpeting. So, the 50 percent dislodgeability used in risk assessment is greater than 10 times what it really is.

Mr. GOODLATTE. Thank you. The gentleman from Arkansas, Mr. Berry.

Mr. BERRY. They tell an old story in Arkansas about the board of directors that was going to hire a new CEO, and they brought in an engineer and they interviewed him and asked him what was 2 and 2, and he got his slide rule out and he said, "Well, it depends on whether it is a plus 2 or minus 2." So they let him go and they brought in an accountant, and they interviewed him and they asked him what was 2 and 2, and he said, "Well, it depends on whether it is a credit 2 or a debit 2." Then they brought in one of the chief political appointees in the EPA and asked him what is 2 and 2. He looked under the table, behind the curtains, in the closet, under the chairs, then he looked at the Board of Directors and he said, "What do you want it to be?" And that is the feeling I have gotten today, and have had for several weeks now as we have seen this whole process basically crumble and fall apart, and I just wonder if you all agree with that?

Mr. ENGEL. In order? It was pretty obvious today, Congressman, that a lot of that is reflected in everybody's comments. I am part of that TRAC committee, and when I first entered that TRAC activity, I could not see for one moment how that could function, let alone accomplish something. Much to my surprise, there was some accomplishment and there was some interaction that was positive.

So, number one, I think the TRAC process comes to an end with one more meeting and, number two, I think it is disheartening to see a rush to judgment.

Mr. JAMES. The comment I would make is that if the EPA does rush to judgment on some of these products and the real data from the urban uses of pesticides is not used, it could have a terribly adverse effect on the farming use of pesticides because urban use it because is where the real assumptions are being made, apparently, by the agency at this time, or will be shortly when the next set of decisions are made. There is no indication that they are going to either tell us all the data they need or use all the data we are going to make available to EPA when we get it available, and that is going to take some time. Those quick decisions are going to be made apparently, and if that happens then the agency is going to be using overstated risk evaluations and assumptions that are not valid, which could and be easily disproven if given the opportunity. Using overstated rick information will cause decisions to be made by companies, whether voluntary or otherwise, which can have a very adverse effect on uses for agriculture.

The fact of the matter is, the uses of urban pesticides are very profitable for our companies, and so those companies are going to have to decide whether a use on corn more important than a use for lawn care, or is the use on lawn care more important than on corn? We don't want companies to have to make that decision because we want the EPA and the USDA to use our good information so that the final answer is solid and reliable, and then the decision can be made and the proper decisions can be made, but we fear that bad information used by the agency on the urban use of pesticides could not only hurt our uses, but could hurt agriculture as well.

Mr. GARDNER. I would just echo what Mr. James said. As a farmer, frankly, I am worried as hell. I think we set a precedence yesterday with what happened. Anytime that a regulatory agency does not use sound science in making those decisions, and they take those chemicals off the market, that hurts us as farmers and our business, and I am really concerned about the future and this process. I hope some adjustment can be made.

Mr. WICHTERMAN. Mr. Berry, the only comment that I would like to make in reference to what I do for a living in public health vector control—and, unfortunately, you were out of the room when I presented a while ago—but in our little corner of the world regarding the public health provisions of the act, we have to have consultation with the Department of Health and Human Services, to perform the consultative and the data collection with respect to the public health issues. When EPA requests information on data gaps to be filled, and also whether this is a worthy pesticide to be defended, then the Secretary of Health and Human Services must comment.

And our problem over the last 3 years—and we have worked very hard at the American Mosquito Control Association's level—is that we keep hearing that this is an unfunded mandate at HHS and, therefore, unless Congress appropriates the money, it will not be forthcoming. And today we do not have anything to bring before you as far as what constructive discussions may have teken place with this particular department over the last 3 years. There is some consultation going on, agreed, but not to the degree that needs to be brought to the level in my testimony where we have got three public health pesticide products that are in the phase 4 of the pilot process, and to date EPA has identified that it is going to cost $7 million to fill these data gaps. And the responsibility of HHS is to support the data collection, like the IR–4 program administered by the USDA is doing currently. They have been doing it successfully for 37 years. We are trying to work into that same scenario, we are not trying to reinvent the wheel, and we cannot get that program started.

Mr. GOODLATTE. Thank you, Mr. Berry. The gentleman from Illinois, Mr. Ewing.

Mr. EWING. Thank you, Mr. Chairman. Mr. Gray, you mentioned in your testimony—and I am sorry that I missed some of your other testimony—that there were sometimes damage to be done by not using the chemicals, that there could be more harm that would result from not having the chemicals to protect us from disease and other things.

Do you think that will show up in any meaningful way with what the EPA has done, or the TRAC that they are on? Do you think we will see that, or will it be kind of below the radar screen?

Mr. GRAY. I think that depends on the scale of the actions that the EPA takes. The analysis that we are doing that looks at what would happen if all of the organophosphates and carbamates were banned, that is something that was talked about early in the process—in fact, was mentioned on National Public Radio yesterday, in response to the azinphos methyl and the methyl parathion actions.

We look at that. We can't even say that we are getting any public health benefit from a ban on all of them. And we can point to some

things that will occur that will have public health harms, that when I look at it, look to me like they will offset anything we would get and perhaps cause problems.

One of the biggest effects, frankly, is changes in nutrition because prices will increase, and we have data that was developed by colleagues at Auburn University showing changes in nutrition, the intake of a variety of nutrients by people in the population. And we see that a lot of nutrients that we know fight disease, that enhance health, will go down. Their consumption will decrease. That will have a health effect. They will be hard to find. They will be hard to monitor. I mean, we are talking about 270 million people, and we are talking about changes in some. It will be hard to see.

We also see that there will be farmers put out of business. That has effects, income effects on farmers, have very real effects on the health of their families, and that we know will occur.

So, yes, I do believe that there will be effects that will offset and perhaps even overwhelm the benefits that might come from action against this particular category of pesticides.

Mr. EWING. One of the concerns that I have—and I think I have seen it play out in other areas of regulation—the regulation really doesn't achieve the goal, and there are kind of insidious things that happen, but they happen so slowly to us and the public that we don't react to it with any great vigor. Prices of something go up, are driven up, and we just think it is inflation and we do with less, or whatever.

But you are saying that you don't anticipate that we are going to have an outbreak of any particular disease that could be attributed to this, that might really focus attention on what the EPA has done.

Mr. GRAY. I think that is unlikely, just like it is going to be impossible to see any benefit from what the EPA has done. It will be very hard to say.

Mr. EWING. Does someone else wish——

Mr. WICHTERMAN. Yes, sir. I would disagree with that, respectfully. In our particular situation with organophosphates, we only have five that we can currently use for mosquito and vector control in the United States. And, unfortunately, out of that five, we have resistance to some of those organophosphates.

In the State of Florida where I come from, we have resistance to malathion, for example, on our salt marsh mosquitoes. Well, as you are well aware, the coast of Florida is lined with salt marshes, and that is where these mosquitoes are prolific. And if we do lose an organophosphate in our situation, we are at a loss, and we do need to have all of our organophosphates that currently remain in our arsenal, because the mosquitoes, may select the genes for resistance to a particular pesticide; therefore the mosquitoes will become immune. Consequently, if we cannot alternate our pesticides between the synthetic pyrethroids, for example, and the organophosphates, and perhaps the carbamates, we are going to be selecting the genes for resistance much more quickly.

Mr. EWING. So you could really have a counter-effect.

Mr. WICHTERMAN. We would have an epidemic.

Mr. EWING. Caused by the mosquitoes.

Mr. WICHTERMAN. Yes.

Mr. EWING. To date, have we had any type of epidemic or any case after case of children or adults that have been harmed by these chemicals in the way they are currently being used?

Mr. WICHTERMAN. I am not aware of this. In our mosquito and vector control programs throughout the United States, I am not aware of any.

Mr. EWING. So the action is really kind of one to protect us from this harm that may be out there?

Mr. ENGEL. It is real. It is not that may be out there, it is real. Let me give you some numbers. In your State of Virginia this past year, you had 62 cases of Lyme Disease, 54 cases of Rocky Mountain Spotted Fever, 60 cases of malaria. Two of those three were caused by mosquitoes, and they could have been prevented with the proper use of an insect repellant or mosquito control device. I can do it for all 50, and you have it for your records.

Mr. EWING. Thank you. My time is up.

Mr. GOODLATTE. Thank you, Mr. Ewing. The gentleman from California, Mr. Pombo.

Mr. POMBO. Thank you, Mr. Chairman. This has been a fascinating panel. Mr. Wichterman, before I get to the questions, you talked about the budget process, and I can tell you that it is amazing to me the things that they can find money to spend on, if they want to. And I think all of us up here could give you lists of things that we found out that they spent money on, that not a one of us ever would have voted for. But if it is something they want to spend money on, they seem to have a lot of it.

One of the things that concerns me about the testimony that I have heard from this panel is that the only thing standing between the public and a malaria outbreak or an encephalitis outbreak is Mr. Wichterman and the people that he represents here. The only thing standing between the public and having their homes overrun with cockroaches and pests is Mr. Rosenberg and the people he represents. And the administration knows that. The people down at EPA know that. They are not that dumb that they can't figure that out.

Now, this is where Mr. Gardner ought to be real concerned because most of the public think that these bands on chemicals and all these horrible things that we are talking about here today only affect him. They don't think it affects them. So, when it comes right down to it, he is the one that is not going to be able to use these pest control methods, not you guys, because they know that there would be a revolution on their hands if, all of a sudden, you guys couldn't treat these people's homes.

I know I go down and I talk to my sister-in-law, and when we get on the topic of pesticides, she thinks they are horrible, but she calls in the Orkin guy who comes in twice a month to kill all the ants around the house. That is OK. And, unfortunately, most of the public is in that position. And that is what happens out there.

Mr. Gray, I don't know if you had the good fortune of being able to read some of the press releases that were sent out yesterday after that, but you look like a fairly reasonable guy, and I looked at your background and you seem to be fairly well-educated, and I am just shocked that you don't care about poisoning your kids by giving them all these horrible fruits and vegetables. And in my

opening statement, that was more my concern, is that that is the message that they were sending to the public and, unfortunately, if you saw the media last night or read any of the papers this morning, that was pretty much the message that they were sending the American public out there.

Mr. GRAY. I agree, and I think that is why it is important that people like me, people in the public health world that know the science, know the risk, not only talk the talk but walk the walk.

When I talk to my sisters about their kids, I say, "Don't worry about it." They see me showing that I not only say it but I believe it and I act it, how we get that message out more broadly, I don't know.

Mr. POMBO. Well, a big part of it is having people like you that are willing to speak out, and having people like all of you that are willing to speak out and point out some of the fallacies.

Let me ask you a direct question in terms of these assumptions that are out there. I have tried to sit down with some of the scientists out there that understand this, and walk my way through this, so that I can try to understand the rationale that EPA is using for this. And for the life of me, I can't understand how they come up with these assumptions and then come before us and try to defend them, because some of these assumptions that they are basing their decisions on are way out there.

Mr. GRAY. I think you are exactly right, and one of the things—I mean, we take a whole course to walk students through these assumptions, to understand what is done. I think one of the problems is the way in which these risks are being assessed is that there is a notion that we are being health protected because we make up the wildest, worst case assumptions we can. We make the most extreme assumptions we can because there is sort of nothing bad about going too far, because we are just being more health protected. But we are forgetting that when we do that, it is just completely disrupting our ability to make rational decisions, to make comparisons about different pest control options, about different uses of the same pesticides. There is a notion that being conservative is health protective, and it is wrong. And, in fact, my testimony, other things I have written, will show you that, in fact, we can make things worse.

So, I think the problem is we are willing to let people say assumptions are OK because they are conservative, and we can't do that. We have to say they are scientifically approved. And that is why I think we need to make progress.

Mr. POMBO. But in your profession when you make assumptions that are out there, is that more based upon old technology when maybe we couldn't measure parts in a particular product so intricately that we can today? When we did FQPA, the whole idea was we were going to use modern technology, and we were trying to get away from an outdated law that was 40 years old and trying to come up with modern technology, and yet it seems that the science that is being used in this particular case is based upon some of those old ideas that we wanted to get away from.

Mr. GRAY. Actually, I think you have hit the nail on the head. It is old technology on every angle. On the science and on the analysis, it is old technology. I think FQPA contains a lot of what you

would almost consider technology forcing aspects for risk assessment. It will make us do a better job, but in order to do that we have to be receptive to the science and use the best science available, and not try to shoehorn our old methods, our old technology, into this new piece of legislation.

Mr. POMBO. I agree with you, and this is where when it comes to the science that's being used, I have got a real problem. If we stuck to science, whatever the outcome is, I think we could all agree. And everybody has testified in previous panels and here, that if there is a chemical that is truly dangerous, if there is an imminent risk, it is off the market. And everybody has agreed with that.

The problem is that when you interject a political agenda or politics in general into science, you end up with decisions like we are faced with right now, that a political decision was made versus a scientific decision, because when I have people coming into my office that aren't complaining about the policy, they are not complaining about the politics, they are complaining about the science.

Mr. GRAY. Frankly, that worries me very much as a scientist and a risk analyst. It should worry EPA, as an agency that relies on science. I agree with you completely, and it worries me a lot for the credibility of all of our decisionmaking on health and environmental issues.

Mr. POMBO. Well, I thank you very much for your testimony. I thank all of you. This has been a very, very good panel, and when the committee record is put together, this is something I will put to good use, the testimony that we received here today. Thank you all very much.

Mr. GOODLATTE. Thank you. Mr. Rosenberg, let me ask you, do you believe that the decisions that the EPA makes in regard to agricultural pesticides have a potential impact on the availability of the tools that your pest control operators use to prevent the spread of disease due to all the insects and rodents and so on that you have to deal with?

Mr. ROSENBERG. Mr. Chairman, I appreciate that question. I think it works both ways. Certainly, the decisions they are making about dietary exposure will impact the availability of products for the folks that I represent, who deal with termites and cockroaches and fleas, and those kind of things.

If I were a farmer, though, I would be more concerned about the decisions they are going to make on the products used in the urban sector because those risk assumptions are so wildly exaggerated that, in fact, they are going to eat up these huge chunks of that little risk cup and guys like Allen represents are going to have to make a decision, if it is profitable to stay in the urban sector, then I may only be able to stay in the urban sector and may not be able to sell to the agricultural sector. So, I don't know who is going to come out of this worse, but we are very much dependent on their decisions, they on ours.

Mr. GOODLATTE. Thank you. Mr. Berry, do you have any other questions?

Mr. BERRY. No.

Mr. POMBO. I could go on all day.

Mr. GOODLATTE. The gentleman from California says he could go on all day, and we are already into the evening, so we are proving that to be right, and I agree with him.

I want to thank all of you, you have made a tremendous contribution to the work of this committee and establishing a sound basis for the legislation that we originally wrote, and a sound basis for carrying it forward in a way that enables us to receive all of the benefits of safe products and still effectively screen out those that are unsafe. And, Dr. Gray, I think you make a very important contribution in terms of the need to take into account all of the risks that are confronted here, not only the risk of direct exposure to these products, which is a risk that we definitely want to take into account and eliminate those that are harmful, but we have to weigh those risks against all of the benefits that come from making sure that we have a healthy, safe, affordable food supply, that children and others have a nutritious well balanced diet, that if we don't have an affordable food supply they won't get, and that these same products are often used to combat other sources of disease that Mr. Goddard and Mr. Wichterman and Mr. Rosenberg are dedicated to fighting, and we don't want to take those tools away from you. So, I thank you all for your contribution, and I hope that we will be able to continue to press forward to get a good implementation of the FQPA.

With that, I would ask unanimous consent to allow the record of today's hearing to remain open for 10 days to receive additional material and supplementary written responses from witnesses to any question posed by any member of the panel. Without objection, it is so ordered, and this hearing of the Subcommittee on Department Operations, Oversight, Nutrition and Forestry is adjourned.

[Whereupon, at 6:10 p.m., the subcommittee was adjourned, subject to the call of the chair.]

[Material submitted for inclusion in the record follows:]

STATEMENT OF KEVIN GARDNER

Good morning, Mr. Chairman. I would like to thank you and the members of the subcommittee for holding this hearing and your continued work on this very important issue. I am Kevin Gardner, chairman of the American Farm Bureau Federation's Young Farmer and Rancher Committee. Together, with my wife Glenna and our four young children, we operate a corn, wheat, soybean, tobacco and alfalfa hay farm in Barren County, KY.

Like almost everybody else, Farm Bureau supported passage of the Food Quality Protection Act (FQPA) of 1996. With today being the three-year anniversary of FQPA's passage, how the act is being implemented is causing great concern. We are now being told that farmers must mitigate risk for many critical pesticide tools, some of which have been used safely for over 40 years. As we witnessed yesterday, this means the outright cancellation of uses and dramatically altering use patterns of others.

As a younger member of the farming community and an individual now only beginning to invest in the business of food production, I need to be assured that safe crop protection tools I depend on will be available to me when I need them. Starting out in farming is not an inexpensive undertaking. It involves, as you all know, a substantial amount of investment and risk. My creditors are relying on me to produce a product that has value so that I can repay them.

I plan to farm for years to come. I also plan to support my family and supply consumers with safe and affordable products. But actions taken yesterday by EPA Administrator Browner are unjustified and have the potential to cause severe harm to many in agriculture with no increase in consumer safety. As for children's safety, my wife and I shop at the same grocery stores and serve to our children the same

foods non-farmers buy. Our food supply is safe and our ability to produce the safest, most abundant and affordable food on earth is unequaled. Our regulatory system is the most rigorous in the world.

The organophosphates represent the single most important class of insecticides used in the United States and are the first target of EPA. They are also essential to integrated pest management (IPM) programs. With a farm economic crisis brought on by historically low prices, I believe the agency has acted irresponsibly.

Beyond the immediate farm level impact, yesterday's actions give me great concern because of the lack of any coherent objective or science-driven process. A year ago Vice President Gore, taking a cue from this committee, issued a memorandum with four basic principles to guide the implementation of FQPA. They are: sound science, transparency, transition for agriculture, and public input. We in agriculture welcomed that attempt to establish a rational meaningful process. Until recently it seemed to be succeeding in bringing some order to a very complex and difficult task. I believe the four principles are sound and based on common-sense. But as a farmer they take on additional meaning to me.

The first principle is transparency. Growers and the non-agricultural pesticide user community trusted that the implementation process for the FQPA would be transparent and follow established administrative procedures for Federal rules and regulations. It has not.

Over a year and half after the Vice President's memorandum, and the first deadline now here, not a single science policy paper has been finalized. How can the agency be making fair pesticide risk assessments at the same time they are still seeking public comment for that same process? Without these policies can anyone possibly understand the process?

The second principle is transition and the availability of safe pest control products for farmers and other users. Transition in agriculture is an ever-present event. I am constantly adopting new practices on my farm. But I base those on sound information, not guess work and assumptions. I need to stay abreast of the latest technology and practices and then make reasonable decisions. As a farmer, transition to me means identifying new crop protection products, practices and technologies as alternatives for products that show unreasonable risk. The alternatives must be safe, effective and economically viable. My creditors and my wife would frown on my acceptance, with blind faith and a wink and a nod from EPA, that an alternative will be available down the road.

The third principle is sound science. I don't base decisions I make on my farm on default assumptions and shoddy science, and neither should the EPA. They are responsible for decisions that will affect my family and my farm for years to come. Prior to FQPA, the focus was on dietary risk. After the FQPA, additional exposures must now be considered such as drinking water and residential exposure. These provisions make sense only if the agency uses real data and reliable information. To do otherwise doesn't make the regulatory system any more protective of public health, only more difficult to navigate.

In light of the new requirements of FQPA, real data takes on even more importance. Worst case assumption about agriculture use when added to similar unrealistic default assumption from the structural pest control community, and from drinking water models total theoretical risk, is usually well above the safety standard. The agriculture and the urban pest control industry depend on each other and the agency to use real-world data, not default assumptions.

With real data, we can replace these worst case assumptions, but it takes time and cooperation from EPA and USDA.

Farm Bureau supports corrective legislation to ensure fair and science based implementation of the FQPA. We want to thank all the members of this committee for their help over the past 3 years and continuing assistance in achieving a fair and balanced implementation of FQPA.

We don't believe that by passing the FQPA, Congress intended for the EPA and USDA to make hasty decisions based on theoretical risk that would unfairly and unjustly affect all users of pest control products. Instead, we believe and agree with Congress that sound science and a fair process is the foundation of this law. These themes are consistent with our views and with the Vice President's memorandum.

EPA made decisions for two organophoshates yesterday. These decisions are being made outside the reassessment process that is slowly being built and are based on unrealistic default assumptions, unclear science policies, and only serve to falsely scare the public about the safety of their food.

In conclusion, our society derives significant benefits from the safe use of pesticides on farms and in the community at large. Last month, the U.S. Department of Health and Human Services (HHS), released a new report documenting major im-

provements in American's health and sighting, and I quote, the "consumption of five fruits and vegetables a day," as one of the major contributors.

There is a lot of good news for the American food consumer. The supply of food is bountiful, quality is unparalleled, variety is ever expanding and prices are reasonable. The U.S. system is unrivaled in the world. Our quality of life and health are evidence to this. Our hope is that FQPA will allow us to build on these successes.

Thank you for holding this important hearing and for your attention to our concerns.

STATEMENT OF GEORGE WICHTERMAN

I am George Wichterman, chairman of the Public Health Pesticide Working Group for the American Mosquito Control Association, Past President of the Florida Mosquito Control Association and Senior Entomologist with the Lee County Mosquito Control District in Fort Myers, Florida. I am also a member of the FQPA Tolerance Reassessment Advisory Committee (TRAC) representing public health vector control and a member of the Pesticide Environmental Stewardship Program (PESP) for the AMCA. Accompanying me are Mr. Joseph Kertesz, AMCA Mid Atlantic Regional Director, Hampton, Virginia, and past president of the Virginia Mosquito Control Association, and Mrs. Judy Hansen, Past President of the AMCA and current president of the New Jersey Mosquito Control Association. I want to express our appreciation to Chairman Goodlatte for his leadership in holding these important hearings on the implementation of the Food Quality Protection Act, especially focusing on the importance of public health pesticides in preserving and protecting our nations public health.

The American Mosquito Control Association is a non-profit international association of individuals and organization (over 2000 members) interested in mosquito and other vector control. Our mission is to provide leadership, information, and education leading to enhancement of health, and quality of life through the suppression of mosquito and other vector transmitted diseases and the reduction of annoyance levels caused by mosquitoes and other vectors and pests of public health importance.

I regret that as a member of the public health community I can not fairly report that we have made significant progress in implementing the public health provisions of the 1996 Act. Specifically, HHS has not established a home for this important program. Moreover, HHS has not sought to appropriate the funds necessary to conduct the studies to maintain the arsenal of public health pesticides we believe are necessary to fight vector- borne diseases such as encephalitis which is increasing. Without this arsenal, we are at risk of insect resistance.

Before 1996, the focus of FIFRA and EPA's pesticide program was on agricultural pesticides. Most of the multinational companies develop and expand active ingredients for their agricultural use since that is where the large volume is. Mosquito control programs use comparatively small amounts of pesticides in adulticiding and larviciding programs. The manufacturers of active ingredients historically have been reluctant to develop the aquatic toxicity and aquatic fate data required to maintain the registration of mosquito control products. Under EPA's regulations without these data, the Agency will not "reregister" the mosquito control use. If we don't have a variety of pesticides to use in our programs, we face the prospect of mosquitoes developing resistance.

One of the objectives of FQPA was to require EPA, in consultation with HHS, to consider the unique needs and benefits of public health pesticides and for HHS to conduct testing necessary to support the continued registration of public health pesticides. Congress thus envisioned HHS serving a critical role in the preservation of public health pesticides. HHS unfortunately has not stepped up to the task. With the incidence of mosquito-borne diseases increasing, placing at risk children and the elderly, an ironic development, especially since FQPA was born out of concern of children's health. I urge this committee and Congress to remind the Secretary of HHS of the Department's role under FQPA.

IMPORTANCE OF PUBLIC HEALTH PESTICIDES

Public health pesticides and their important uses are truly unique products with enormous health benefits for our nation, our children and our senior citizens. Mosquito-borne viruses (e.g. St. Louis encephalitis, eastern equine encephalitis, western equine encephalitis, dengue, and dengue hemorrhagic fever) are increasing threats to our public health. Public health pesticides are designed to protect the public from pests such as mosquitoes, fleas, flies, cockroaches, rats, mice, ticks, bacteria, head

lice and viruses. Vector- borne diseases include encephalitis, cockroach asthma, salmonellosis, legionnaire's disease, malaria, hantavirus, plague, and tularemia.

If we as a nation are going to promote public health in America, protect current and future generations, and enhance the quality of life, it is important that we protect public health pesticides products and their uses. Currently, there are not any new public health pesticides being developed by the chemical companies. As a result we can not afford to have these remaining products discontinued or eliminated, and we must make every effort to adopt a mitigation strategy so that we can retain these important uses. As public health officials from across the nation, we must have effective, yet affordable, pest control products to protect our people and our society, especially the most vulnerable segments of our population—our children and our senior citizens.

EXPEDITE THE PUBLIC HEALTH PROVISIONS OF THE FOOD QUALITY PROTECTION ACT OF 1996

The Food Quality Protection Act specified several new regulatory obligations for the Environmental Protection Agency (EPA), and the Department of Health and Human Services Department (HHS), requiring a new regulatory liaison and memorandum of understanding between the two agencies. Despite considerable effort, however, the two agencies have still not finalized a Memorandum of Understanding (MOU) or determined how this cooperative arrangement will be undertaken. We would urge both agencies to finalize these agreements so that the regulatory responsibilities are clear. EPA has taken the initiative in this regard and appointed a public health coordinator including a team of officials to address these issues with respect to FQPA; however, as noted, HHS has not implemented FQPA as we approach the third anniversary of the act. Rather, HHS views its responsibilities under the act as an unfunded mandate.

For more than 2 years, EPA, in consultation with HHS and the U.S. Department of Agriculture, has worked on the publication of a Public Health Pest List , according to the new requirements of FQPA. We would urge the EPA to expedite the publication of this comprehensive list, with a ninety day comment period, so that all public health officials could comment on the list.

In addition, section 25 (a) (1) of FIFRA calls for EPA to identify the various classes of pesticides, including agricultural, nonagricultural, and public health pesticides. If EPA is to consider the difference in concept and usage when making pesticide regulatory decisions, then the Agency must complete classifying pesticides, including public health pesticides. It would seem logical that products that include public health pests on their label could be defined as public health pesticides.

Public health pesticides provide many benefits to our nation, such as preventing the spread of infectious diseases, improving the quality of our lives, and protecting our most vulnerable subpopulations such as our children and our senior citizens. The provisions of FQPA provide that HHS should provide available benefits and use information or an analysis thereof to the EPA. It is important that EPA have the benefit of HHS's assessment during the Agency's regulatory review of public health pesticides. We would urge both agencies to work out this important exchange of benefit information.

As noted, one of the most important provisions of the FQPA called for the establishment of the Public Health Pesticide Data Collection Program. The development of these data are essential to maintain a viable mix of mosquito control products. Under FIFRA Section 4 (n), entitled Authorization of Funds to Develop Public Health Data, the new FQPA requirements authorized the appropriations of $12 million for fiscal year 1997 and future years. HHS has not requested these funds or developed a program for the development of these data, nor it is clear that such a funding request will be made in fiscal year 2001. It is important that this public health pesticide data collection program be started as quickly as possible since there are three public health pesticide products being reviewed by EPA in their pilot process and the Agency has identified data gaps for each. It has been determined by individuals within EPA and HHS that $7,000,000 would be necessary to satisfy these data requirements in order that reregistration may be completed for these compounds. Unfortunately HHS has been unable not only to establish a home for this pesticide data collection program, but also has not provided the necessary funds to support these orphan use public health pesticide products. USDA's IR–4 program under which that Department supports residue testing to assure the continued registration and tolerances for minor crop pesticides is proof that a Department can effectively generate pesticide data important to achieve a public goal.

Many public health products will disappear if funding for the Public Health Pesticide Data Collection Program is not approved. These products, of which many are

low volume, low profit, products, will be lost in the registration and reregistration process because of economic reasons. Simply, the cost of generating the necessary data to continue these registrations far exceeds the return on sales of these products. These funds could be used at land grant universities and consulting laboratories to promote research on disease carrying vectors that are important to maintaining the nation's public health.

We respectfully urge the EPA, HHS, and the Clinton Administration to collectively work together to implement the Public Health Pesticide Data Collection Program, so that the program can begin at least by the beginning of fiscal year 2001.

Consequently, we at AMCA believe it is important to fully implement the public health provisions of the Food Quality Protection Act,, including but not limited to the following: (1) appropriation of funds, (2) establishing a program home within HHS, (3) execution of the Memorandum of Understanding (MOU), (2) Completion of the Pest List, (3) Classification of Public Health Pesticide Products, (4) Establishment of the benefits of public health pesticides, and (5) the establishment of the Public Health Pesticide Data Collection Program with the necessary funding.

Tolerance Reassessment and the Implementation of FQPA

In devising a method of instituting the new health-based safety standard of FQPA, EPA has established a theoretical "risk cup" which can be thought of as a cup filled with all pesticides with a common mode of toxicity. The theoretical risk cup, however, may not have adequate space to preserve many beneficial products—particularly minor use pesticides used in the control of public health pests such as mosquitoes, ticks, flies, roaches, rats, mice, bacteria, viruses, and other disease-carrying insects. In essence, many of these currently registered uses may be lost.

FQPA decisions need to be based on a reliable data base rather than default assumptions of maximum exposure and use. AMCA believes that many a number of valuable and beneficial public health pesticides stand in jeopardy of being canceled by EPA because the Agency may be basing its determinations on overstated assumptions of pesticide usage and inflated estimates of the potential risk associated with exposure. Within the public health community, there is a growing concern that EPA is not basing its product decisions on a complete and comprehensive database. Rather there is speculation that the Agency is relying on inadequate data and overly conservative risk assumptions in determining whether certain categories of pesticides pose an unacceptable risk to human health.

The widespread cancellation of a number of important public health pesticide products currently available would have a devastating impact on public health officials nationwide. By reducing or eliminating the important public health pesticide tools, public health officials will face insurmountable obstacles to protect the nation's public health, especially if there is no viable alternative. This potentially disastrous situation may be averted if the EPA bases its regulatory decisions on a complete set of information for each pesticide product. If data gaps exist for public health pesticide uses, such as exposure data, the Agency has full authority under FIFRA's Data Call-in provisions to request the generation of this much needed data.

To further facilitate the development of use data and exposure data on mosquito control products, the American Mosquito Control Association, in conjunction with EPA, put together a survey of public health pesticide uses in the mosquito control districts across the Nation during the spring of 1998. Working with EPA officials and the Biological and Economics Analysis Division (BEAD), AMCA officials designed a survey to obtain a comprehensive pattern of use for all mosquito control products. We were interested in obtaining use rates, acres treated, and how often applications were made on urban, rural, or wildlife refuge areas. We were attempting to establish use patterns, levels of exposure, and the amount of resistance that might have occurred. This study has been completed in 1998, collated by the EPA's outside contractor, and is presently being reviewed by BEAD. We are hopeful that this new use information will be helpful to the EPA when it makes it decisions about risk assessment, risk management, and risk mitigation for public health pesticide products, especially the organophosphate (OP) insecticides.

Benefits of Organophosphate Insecticides for Public Health

Organophosphate (OP) insecticides are one of the most widely used pesticides in the United States. For almost 30 years, these effective, yet affordable, pesticides have been utilized to control public health pests, especially mosquitoes. These pesticide products are usually applied at low dosage rates against public health pests, have low levels of exposure, and are not persistent in the environment. They are an effective part of an IPM program.

Many of the OP compounds are important pesticide tools for professional public health officials. Five OP compounds are used for mosquito control purposes. Prevention is a key element in controlling mosquitoes and the effective use of larvicides is especially cost and time efficient because immature mosquitoes are usually highly concentrated and immobile. Mosquito control districts use temephos as a larvicide to control young and immature mosquitoes. This product is especially effective against salt marsh mosquitoes and as a vector control device for St. Louis encephalitis.

It is equally important that four OP compounds are utilized as adulticides, including Chlorpyrifos, Fenthion, Malathion and Naled. Chlorpyrifos is used against adult mosquitoes throughout the United States. Fenthion is registered as a mosquito adulticide only within the State of Florida, but is used elsewhere against other public health pests. Malathion is one of the most widely used pesticides in the United States, with multiple uses for crop protection, non-agricultural uses, and public health uses. It is used for medfly eradication in Florida and California, in urban and rural areas, because of its low dosage and low exposure elements. In this decade, it has been used after numerous natural disasters, including hurricanes in the Carolinas, and after devastating Midwestern floods. And Naled has been used extensively as a public health pesticide to reduce adult mosquito populations.

Professional mosquito control officials usually utilize an Integrated Pest Management (IPM) approach, which has been endorsed by EPA, USDA, and CDC. IPM practices frequently focus on habitat modification, especially larval habitats and utilize pesticides to supplement other approaches. When pesticides are used, they are influenced by several factors such as: (1) local mosquito species, (2) application requirements (air, boat, truck, and backpack), (3) time of day (pre-dawn or after sunset), (4) to minimize impact on non-target species, (5) an analysis of scientifically conducted field surveillance, (6) cost effectiveness, and (7) the threat of mosquito-borne viruses.

In view of the important role that OP compounds have for the professional mosquito control programs in the United States and the efficient and effective manner in which they are applied, it is important to retain the public health uses of OPs. But retaining only the public health uses of the OPs will not be sufficient to economically support the retention of a particular pesticide product. The low volume, low profits generated by most public health uses, compared to most crop protection uses, are an insufficient economic incentive to support the reregistration of an OP. A registrant is unlikely to spend $10 or $20 million for the reregistration of an OP, just to save the public health uses.

Resistance to Pyrethroids, and the Impact on OPs

Under normal circumstances, public health pesticides fall into four classes: (1) organophosphates, (2) pyrethroids, (3) carbamates (only one labeled adulticide remains-because the registrants are not supporting the reregistrations) and (4) natural biocides . For all practical purposes, however, the pyrethroids and the organophosphates are the only ones in general use.

These pesticide products affect insects in different ways. In general, the classes of insecticides have different modes of action. Thus, each class of insecticides affects a different physiological activity in insects. This phenomenon, along with other major characteristics, is an important factor in deciding which pesticide to select for operational use. Decisions of this type are routinely made by managers of agencies responsible for protecting the public from nuisance and disease-bearing arthropods.

These same public health officials have to be alert for changes in effectiveness of the pesticide products they are using. It is not uncommon for pesticide applications to exert selection pressures on the target insect populations, in which those few with the appropriate physiological or behavioral mechanism are capable of detoxifying or otherwise escaping the effect of the pesticide and therefore, survive exposure. When this escape occurs and the selection pressure continues because of repeated applications of the same material or one with a similar mode of action, there is a gradual buildup of individuals in the insect populations that can escape the effect of the pesticide. As a result of this selection process, eventually most of the individuals in the populations can escape the effect of the pesticide. Sometimes the insecticide resistance triggered by the escape mechanism extends to the entire class of insecticide. If the entire class of insecticides can escape, then neither the specific pesticide that caused the selection, nor other members of the same class of pesticides will be effective against this species of insect.

In the United States and on a global basis, selection of this type has occurred in over 500 insects of economic importance! Often substituted pesticide products from the same classes of insecticides are initially effective, but become ineffective very

rapidly because of the escape mechanism that has been selected in the target species. Under these circumstances, the entire class of insecticides rapidly becomes useless against that species because of insecticide resistance.

Occasionally the exposure of a public health pest, an insect, occurs not as a result of control measures against that specific insect, but in response to incidental exposure to insecticide applications intended for crop protection purposes. Nevertheless, the usefulness of the pesticide and/or the class of pesticide may be lost for public health use. Since there are only a few insecticides registered for public health uses, it is a very serious setback when an insecticide or class of insecticides is lost due to resistance. It takes years of research, trying thousands of compounds, before an effective insecticide is discovered, costing upwards of $50 million. Because of the enormous cost involved in finding a new insecticide, virtually none are developed specifically for public health pests. These insecticides are usually developed for crop protection purposes—frequently corn, cotton, soybeans, etc., or for household purposes. Thus only a few become labeled for public health pests.

Because of the development of resistance to one pesticide product or a class of pesticide products, it is essential that multiple classes of public health insecticides be available for attacking public health pests.

There are several practices that the user or public health official can adopt to try to delay the onset of resistance to a specific insecticide or class of insecticides. When the control measures such as biological control or source reduction are not available or are only partially effective, the single most effective approach to prevent resistance is the regular alternation of classes of insecticides. By alternating the mode of action before selection for resistance has progressed too far, it is considered possible to eliminate the few individuals already selected..

With just the organophosphate and pyrethroid classes of insecticides generally available for control of adult public health insects, the loss of either class would eliminate the possibility of managing the prevention of resistance by alternation of adulticides. Thus, if the public health uses of organophosphate compounds were lost due to EPA regulatory action, public health officials would be severely hampered because any hope of delaying and/or preventing the onset of resistance by alternating modes of action against many public health pests would be eliminated. One class (one mode of action) is simply not enough to use good pesticide stewardship by alternating modes of action.

The prolonged continuous use of the one remaining class of insecticide could be expected to produce resistance in target pest populations if some individuals exist that have the capacity to detoxify/escape the pesticide. If that event were to occur, the last effective class of insecticides would then be lost as well.

Thus, should an entire class of insecticides, such as the organophosphates, be removed from the marketplace by EPA regulatory action, the public health official's primary mechanism for preserving insecticide susceptibility among target arthropods would be severely compromised. With but limited commercial interest in the development of public health pesticide products, especially of new alternative class of insecticides with different modes of action, the ability to control the resistant adult pest will be lost.

Since there appears to be some resistance to pyrethroids in Florida, Louisiana, and Ohio, government regulatory action to remove the other alternative product may leave public health officials with a lack of pesticide tools to protect public health. It is imperative to preserve as many classes of insecticides for public health use as is possible in order to:

1. Provide the level of control necessary for protection from vector-borne disease and nuisance pests; and

2. Ensure that good public health pesticide stewardship can be practiced to reduce the likelihood of selection for insecticide resistance by alternating classes of pesticides to take advantage of their different modes of action within the insects' physiological detoxification and escape mechanisms.

Exempt Public Health Uses From Risk Cup Analysis

We at the American Mosquito Control Association urge the Environmental Protection Agency to grant an exemption for public health pesticides and their uses when implementing the risk cup analysis.

The Food Quality Protection Act (FQPA) designated special consideration for public health pesticides when the Congress included the provisions of H. R. 53 (The Public Health Pesticide Protection Act), introduced by Congressmen Cal Dooley and Wally Herger, in H. R. 1627. Consequently, FQPA recognized the truly unique importance of public health pesticides.

First, Section 25 (a) (1) of FIFRA directs the EPA Administrator to "take into account the differences in concept and usage between various classes of pesticides, including public health pesticides, and differences in environmental risk and the appropriate data for evaluating such risk between agricultural, nonagricultural. and public health pesticides."

Second, the public health pesticide provisions of FQPA also directs the EPA Administrator to consult with the Secretary of Health and Human Services "before publishing regulations under this Act (FIFRA) for any public health pesticide . . . In fact, the new public health pesticide provisions include several other areas of consultation between EPA and HHS.

Third, the cancellation provisions of section 6(b) (2(of FIFRA also requires that the Secretary of Health and Human Services "should provide available benefits and use information, or an analysis thereof," to the EPA Administrator as it considers the cancellation or change in pesticide classification for a public health pesticide product.

Fourth, under the authorization of funds to develop public health pesticide data collection (Section 4(n) of FIFRA and subsection 4(n)(3) (Benefits to Support Family), the EPA Administrator and the Secretary of HHS "shall make a determination whether the potential benefits of continued use of the pesticide for public health or public health purposes . . ." warrants the development of public health pesticide data to "support continued registration under Section 3 or reregistration under section 4."

Because of the enormous public health benefits that result from the appropriate use of public health pesticide products, and the important role that OP compounds have for professional mosquito control programs, we at the AMCA respectfully recommend that public health pesticides be exempt from the risk cup analysis and the tolerance reassessment process.

Pesticide Fees

Many public health pesticides require an exemption from tolerance and will also be part of the Agency's reassessment. Importantly, many public health pesticide products contain many low volume inert ingredients, many of which may be discontinued under this proposed pricing structure. If basic manufacturers reformulate their products, they may discontinue public health uses, especially mosquito control uses.

We at AMCA believe that public health pesticide products should be exempt from any tolerance fee so that it may become economically feasible to continue the use of these important public health pesticide products. If the EPA moves ahead to implement the Tolerance Fee Proposal as it is presently drafted, we would urge this subcommittee to hold public hearings on this important issue.

There has been considerable discussion this Spring about a potential Fee for Service Program. We at AMCA are not opposed to a Fee for Service Program, but we believe that public health pesticide products should be exempt from any such program. In essence, there should be no registration fee for any new active ingredient for public health , or any fee for public health new uses. Such fees would discourage research into new uses and establish economic barriers to low volume, low profit public health pesticide products. If the Congress considers a Fee for Service Program, we would respectfully urge this subcommittee to exempt all public health pesticide products from this program.

Legislative Activities

On April 28, 1999, Representative Richard Pombo introduced H.R. 1592, the Regulatory Fairness and Openness Act of 1999. This legislation would require EPA to prepare a written transition analysis and report identifying various assumptions or defaults used by the Agency in making tolerance decisions and non-food pesticide decisions issued during the ten year tolerance reassessment period mandated by FQPA. In addition, the bill contains provisions which would:

- Require EPA to use actual data and scientifically sound information when modifying or revoking a tolerance
- Streamline the Section 18 process

Provide for the monitoring of the international impacts of FQPA on U.S. agricultural commodity sectors

- Direct EPA to issue, via public notice and comment, data guidelines under FIFRA and FFDCA specifying the kinds of information required to support a new or existing tolerance; and
- Establish a new permanent Pesticide Advisory Committee to advise EPA and USDA on FQPA implementation

H.R. 1592 includes additional language which interjects the concepts of benefits and economic considerations in the FQPA decision-making process. First, the bill would direct the EPA Administrator to expedite the review of a product that is likely to provide an effective, economic alternative to the use of a pesticide that has been or is likely to be removed from the market as a result of the new FQPA requirement and for which there is no currently registered effective and economical alternative for which the number of such alternatives is insufficient to avoid problems such as pest resistance.

Second, the measure would require the transition analysis report to include a determination regarding the extent to which an effective and economically alternative to the pesticidal tolerance under review has been approved and whether revocation or modification of the tolerance will result in (1) a significant shift of production within the United States, (2) an increase in imports of corresponding commodities; (3) an increase in pest control costs; (4) pest crop damage and yield loss, including quality degradation, due to the lack of an effective alternative, or (5) a disruption of domestic production of an adequate, wholesome and economical food supply.

H. R. 1592 will ensure that sound science can draw upon the best available data or allow the Agency to call-in the necessary data under their existing authority. We at AMCA believe that this legislation will assist the Agency in making decisions based on sound science not guess science. We at AMCA endorse this legislation and urge the Congress to enact this legislation.

TRAC Should be Retained

In April of 1999, Vice President Al Gore, at the urging of Congressmen Charles Stenholm and Marion Berry recommended a four point plan for the implementation of the FQPA. The result of these collective efforts led the EPA and USDA to establish the Tolerance Reassessment Advisory Committee. The TRAC process has worked very well, creating a balanced dialogue between stakeholders. Importantly, it included many agricultural grower groups, as well as public health officials, thus broadening the viewpoints available to EPA and USDA.

Since this TRAC format has worked so well in representing the diversified opinions concerning the implementation of the FQPA, we at AMCA urge the continuation of the TRAC or a replacement of TRAC with a different entity. There is a real need to continue a dialogue advisory committee of some kind, and we believe that TRAC or a TRAC like entity should be retained.

As an organization of over 2000 public health professionals across the nation, we at the American Mosquito Control Association are dedicated to preserving and protecting the nation's public health. It is important that public health officials have the necessary public health pesticide tools that are effective, yet affordable, pest control products, to protect our people and our nation, especially the most vulnerable segments of our population—our children and our senior citizens.

We again thank the subcommittee for holding these important public health pesticide hearings and greatly appreciate the opportunity to be included in this process. We pledge our willingness to work with this subcommittee to promote, protect, and preserve the nation's public health.

Statement of Bob Rosenberg

Mr. Chairman and members of the Subcommittee, my name is Bob Rosenberg. I am testifying today on behalf of the National Pest Control Association.

NPCA is a 66-year-old trade association headquartered in Northern Virginia. We represent approximately five thousand companies that are in the business of providing structural pest control services.

The pest control industry is quite diverse, comprised of large and small companies alike, located in virtually every city and State in America. Some provide residential pest control services; others provide institutional or commercial pest control services to facilities like restaurants, hotels, hospitals, schools, office buildings and food processing facilities. Among the more common pests we deal with are termites, cockroaches, ants, fleas, ticks, stinging insects, rats, mice and stored product pests that afflict agricultural commodities.

Despite the industry's diversity, we share a common concern about the implementation of the Food Quality Protection Act. We thank you for shedding some light today on one of the most important, but least understood aspects of FQPA; residential or non-agricultural use of pesticides. Though I'm testifying on behalf of the pest control industry, our concern is shared by virtually every other organization that

represents non-agricultural pesticide users, such as golf course superintendents, nurserymen and lawn care operators.

To best understand our concerns, it is important for you to know that FQPA requires that EPA make a determination "that there is a reasonable certainty that no harm will result from aggregate exposure—including all anticipated dietary exposures and all other exposures for which there is reliable information.' In other words, EPA must add up the risks associated with dietary, drinking water and residential exposure.

We believe this is a sensible principle for conducting risk assessments. In fact, NPCA supported the enactment of FQPA in 1996. Our problem is not FQPA itself. We still support the stringent health-based standards established by FQPA. Our concern is with its implementation.

Today is FQPA's third anniversary and EPA is poised to commence its FQPA decision making. Over the next several months EPA will make regulatory decisions about dozens of products used by pest control operators to protect Americans from harmful, destructive and annoying pests. Unfortunately, the Agency plans to make these decisions without the benefit of sound science or reliable data.

The problem, simply put, is: Until the enactment of FQPA, Federal law did not require the production of residential exposure data. Accordingly, very little of this data exists.

EPA has broad statutory authority to compel the manufacturers of residential products to generate data to support the registration of these products. To date, EPA has refused to exercise its "data call-in" authority.

USDA has committed considerable resources to generating real world data to assist EPA with dietary exposure risk assessments. There is, however, no Federal agency generating data for non-agricultural risk assessments.

EPA has made no effort to collect reliable data about residential exposure.

Though EPA has not provided clear guidance, industry has, on its own initiative, begun a number of efforts to generate residential exposure data. This data, however, will not be available for many months or years.

While the TRAC process has made considerable progress in refining the methodology and data necessary for making dietary exposure risk assessments, residential exposure has been virtually neglected in this process.

Instead of the reliable data contemplated by the act, EPA has indicated that it intends to make decisions about residential exposure using what it calls "standard operating procedures." These are highly conservative default assumptions; worst-case scenarios which grossly exaggerate the risk from residential exposure.

When Congress passed FQPA, it fully understood that residential exposure data was not available and carefully crafted the language of the act to ensure that EPA did not make decisions based on hypothetical worst-case scenarios. Again, FQPA provides that EPA take into account "anticipated dietary exposures and all other exposures for which there is reliable information."

(2) EPA openly admits it lacks reliable residential exposure data and a firm grasp of the issue. In a January 4, 1999 Federal Register notice EPA states "Because highly specific, residential exposure data are generally lacking and there is not wide understanding and acceptance of existing models and assumptions"

EPA's apparent decision to ignore the clear intent of Congress will have dire consequences for both agricultural and non-agricultural pesticide users. Because all routes of exposure, agricultural and non-agricultural, alike, will be aggregated into a single small "risk cup," wildly inflated estimates of residential exposure will lead to one of two outcomes:

Pest control operators will lose numerous valuable and often irreplaceable tools to combat cockroaches, termites, rats and other pests that pose very real threats to peoples' health and their homes, or

If a pesticide manufacturer chooses to retain its non-agricultural uses, huge chunks of the "risk cup" will be consumed by these uses, depriving American farmers of access to these products.

We do not intend to be unduly harsh in our indictment of EPA. FQPA is a breathtakingly complex statute which was foisted upon EPA, requiring them to advance the state of science years before its time; a nearly impossible task. Furthermore, the Agency has begun in the last twelve months to make considerable progress in grappling with the complexity of the act. This has manifest itself in the development of dozens of science policy papers; many of which will not be finalized well into next year and some of which have not yet even been published for comment.

EPA is not yet ready to make FQPA regulatory decisions. It has not yet developed a sound scientific base or acquired the reliable data with which to make these decisions. And yet they appear intent on making these decisions anyway. This will have a profoundly negative impact on many millions of Americans. If EPA insists on mov-

ing forward prematurely, then we urge Congress to promptly exercise it legislative prerogative to stop this travesty.

Mr. Chairman, thank you for drawing attention to this issue. I'd be pleased to answer any questions.

STATEMENT OF GEORGE M. GRAY

Chairman Goodlatte, members of the committee, thank you for the opportunity to appear before you today. I am George M. Gray, lecturer in Risk Analysis at the Harvard School of Public Health and Deputy Director of the Harvard Center for Risk Analysis. My comments today are based upon my research and experience as a scientist, risk analyst, and public health professional. These comments are my own and should not be attributed to the Harvard Center for Risk Analysis or School of Public Health.

A fundamental tenet of public health, borrowed from physicians, is "First, do no harm." This notion arises from the recognition that both medical treatments and public health efforts have potential side effects, unintended consequences that may reduce or even cancel out the benefit of the treatment. A well-known example in public health is the treatment of drinking water to destroy disease-causing microorganisms. All of our varied treatment options have concerns about potential side effects, so efforts are made to minimize treatment-related risks while effectively tackling the larger target risk of water-borne disease.

I am here today to tell you that current implementation of the Food Quality Protection Act of 1996 (FQPA) is not paying enough attention to public health side effects of regulatory actions. I do believe the idea of weighing benefits and consequences is embraced in several parts of the FQPA, including its call to ensure that decisions provide"a reasonable certainty that no harm will result" from any action. However, because of a narrow focus and lack of consideration of foreseeable consequences, we cannot be sure that implementation of the FQPA will provide significant public health benefits, and it may even do harm.

Sound management of pesticide risks requires a broad view that goes beyond just pesticide risks and includes the countervailing risks (or side effects) that may arise with any regulatory decision. This risk/risk analysis must evaluate the net change in public health that results from changes in the availability or use of pesticides.

For example, it is clear that banning of a pesticide does not cause the target pest to disappear. Something else, whether another pesticide or other pest management practice, will be used to protect the crop. Of course, a substitute pesticide will have its own toxicity profile and associated potential for risk. You might be surprised to know that decisions about pesticide bans for some or all crops, do not evaluate the risks of the alternatives that will be used. It is clear that these alternatives will reduce the amount of risk reduction that a ban would achieve, and might even cause risk to increase if they are less effective, require more applications, or are more toxic. And substitute pesticides are only one type of countervailing risk. There are risks that may occur to public health or crop production if pest control is weakened in the absence of a particular pesticide. There are public health implications of the economic disruptions that a change in pesticide availability can cause. Evaluating the degree to which countervailing risks may diminish, or even outweigh, the target risk of a regulatory action is critical to ensuring sound implementation of FQPA.

I believe that Congress understood the need to look broadly a public health in considering both agricultural and nonagricultural uses of pesticides. The language in the FQPA clearly addresses many forms of risk/risk tradeoffs in agricultural uses of pesticides and, in some cases, this can easily be extended to public health and nonagricultural uses.

There is a clear recognition of pesticide substitution, and a desire to ensure that alternative pest control methods don't harm public health, in the FQPA provisions for rapid registration of reduced risk pesticides (Section 408(d)(4)(B). This section does not go far enough, in my opinion, because it does not require weighing of the risks of substitute pesticides in decisions affecting the registration of current and new pesticides.

There are other parts of FQPA that should encourage broad thinking about possible risk/risk tradeoffs. In Section 408 (b)(2)(B)(iii)(I) any action restricting the use of a pesticide is required to weigh the risks of the pest being controlled against the risk of the pesticide. This "aflatoxin provision" recognizes the public health benefits provided by some pesticides in controlling pests that carry very real risks of their own. As written, this seems not to apply to nonagricultural uses of pesticides but I would suggest that it should, for example, consider changes in the rate of asthma

induced by cockroach dander that might occur if pesticides used for cockroach control were banned.

The "substantial disruption" subclause in this same section (Section 408 (b)(2)(B)(iii)(II)) has, I believe, important guidance for risk/risk analysis in FQPA implementation. It recognizes that a decision that changes in the availability of a pesticide may have significant public health risks of its own. The committee report clearly identifies the countervailing risks of alternative pest control methods, changes in yield of crops and consequent effects on consumer diets and nutrition through changes in food availability or price. This is wise and farsighted thinking that although the committee report suggests will happen only occasionally, I believe must be an integral part of any decision under FQPA.

It is clear that current implementation of FQPA is not fully considering the risk/risk tradeoffs identified by Congress. I am currently conducting a study examining public health risk/risk tradeoffs with my colleague Professor James K. Hammitt of the Harvard School of Public Health and Harvard Center for Risk Analysis. The American Farm Bureau Federation funds the work.

We are analyzing the public health implications of a ban on the use of all organophosphate and carbamate (OP/Carbamate) pesticides on 14 crops. These compounds are the subject of intense regulatory scrutiny under FQPA and changes in the availability of some of them is highly likely. We recognize that a complete ban is an extreme scenario but it has the analytic virtue of dispensing with the infinite number of "next best" OP/Carbamate for specific combinations of crops and pests should only some number of uses be banned. In addition, this was a scenario that was mentioned early in the debate around implementation of the FQPA. Our analysis relies on data from Dr. Ronald Knutson and his colleagues at Texas A&M University, and economic analyses by Dr. Robert Taylor and colleagues at Auburn University.

Our study has not yet been peer reviewed but there are several preliminary results that I would like to share with you. First, it is difficult to estimate any benefit to public health that would be produced by a ban on OP/Carbamates. This is because of questions about actual exposure to the compounds and the risks of that exposure. Second, countervailing risks will offset any positive effects of that a ban might have and may even make things worse. The pesticides likely to substitute for the OP/Carbamates appear to have similar acute toxicity for farmworkers and have their own toxicologic profiles for consumer exposure. We identify potential increases in natural pesticides, produced by plants to protect themselves, which might occur with an OP/Carbamate ban as an area of concern. Changes in diet due to changes in cost and availability of foods have both negative (e.g., decreased intake of the important nutrient folate) and positive (e.g., decreased intake of fat) effects. Economic changes for consumers and farmers may have the largest effects, with significant predicted increases in mortality based on decreases in disposable income available for health protective actions.

Interestingly, I believe all of these countervailing risks are potentially covered by the "substantial disruption" provisions of the FQPA, but are not part of the current implementation of FQPA.

In closing, my concern with FQPA implementation arises from its narrow focus on pesticide risks while countervailing public health risks are ignored. This clearly occurs with both agricultural and nonagricultural uses of pesticides. To protect public health, we must look broadly at the implications of any regulatory action. I hope in the future, we will see broad consideration of public health risk/risk tradeoffs in pesticide policy to ensure that we are getting the greatest net benefit for our actions.

TESTIMONY OF E. ALLEN JAMES

I am Allen James, executive director of RISE (Responsible Industry for a Sound Environment), the national not-for-profit trade association representing producers and suppliers of specialty pesticides for professional and consumer markets. RISE is affiliated with the American Crop Protection Association, and has more than 150 members who are manufacturers, formulators, and distributors of specialty pesticides, as well as other companies providing services to this industry or associations representing product users.

Industry products are used for public health, general pest control, lawn care, golf courses and other turf areas, nurseries and greenhouses, forestry and for terrestrial and aquatic vegetation management. Most pesticide preducts sold by RISE members contain the same active ingredients as agricultural pesticides.

As this committee is well aware, the Food Quality Protection Act of 1996 dramatically changed the regulation of pesticides. An entirely new paradigm of food pesticide tolerance review requirements came into place, including the need to understand an individuals total potential exposure to a particular pesticide from a variety of exposure sources, including food consumption, non-occupational use and drinking water, plus the potential exposure from all other pesticides with the same mechanism of toxicity. A new food tolerance, or continuation of an existing tolerance, would be set such that total potential exposure to a particular pesticide, or to pesticides that act in the same manner, would not exceed a safe level, determined as the level which would result in "reasonable certainty of no harm."

As you know, problems quickly developed in determining how the U.S. Environmental Protection Agency (EPA) would accomplish this review and what policies and standards would apply. There has recently been some progress in determining appropriate review guidelines, thanks, in part, to the oversight of this committee and to the Tolerance Reassessment Advisory Committee (TRAC) process, but much more EPA guidance is needed. My testimony will focus on the need for better data and policy guidance regarding the urban use of pesticides.

The EPA has acknowledged that the database on pesticide usage and exposure in urban areas, especially in and around homes, is weak at best. In fact, the Agency has very little information about urban pesticide usage patterns. One of the likely reasons for this data gap is that, before FQPA, potential exposure from a particular use was calculated independently of other uses. In urban areas, the potential exposure to a certain pesticide would normally be reasonably low, based on use patterns and product formulations. Limited urban use data were sufficient to make a finding of safety for a product and register it. Years of specialty pesticide usage in urban areas have confirmed the safety of these products.

However, under FQPA, a very precise understanding of the use of, and potential exposure to, all pesticides in urban areas is required, to assure that accurate aggregate and cumulative determinations about these products can be made for food-use pesticides that have urban uses. Failure to develop the necessary database, and the use of exaggerated assumptions, will result in inaccurate total risk calculations. Such erroneous or overstated calculations could have adverse implications for final food tolerance decisions by falsely overflowing the well known risk cup.

Urban use pesticide suppliers are working very hard to develop data which will satisfy the need for accurate information under FQPA. The Outdoor Residential Exposure Task Force (ORETF) was established before passage of FQPA. ORETF has since been expanded to provide broader pesticide exposure and usage information, to provide accurate models which will measure the potential exposure from the use of pesticides on lawns and other turf areas, as well as in gardens. The ORETF was originally formed as a result of a data call-in issued by the EPA to all registrants of pesticide products labeled for application to residential turfgrass. Subsequently, the Agency sanctioned the ORETF's role in generating most of the generic outdoor residential data, and individual members of the ORETF are responsible for generating certain data specific to their own pesticide formulations which are labeled for use on residential lawns and other similar turfgrass areas.

Early information from this task force will be available this fall, but will continue to be developed over the next few years. A similar task force has been developed for indoor pesticide usage and exposure under the auspices of the Chemical Specialties Manufacturers Association.

Together, these two task forces have the potential to greatly improve the understanding of non-occupational pesticide exposure in urban areas. However, as one can imagine, the development of this data will take considerable time, and requires many negotiating sessions with the EPA, to assure that the output will be acceptable and useful to the Agency in making decisions.

As just noted, data development takes time, and is quite costly. Thus, it is critical that the companies develop data that the Agency wants and needs to understand urban pesticide exposure, and that will help the Agency make reasonable scientific decisions based on this information. To date, the kind of guidance and policies needed for companies to move forward has not been forthcoming from the Agency. In fact, in recognizing the lack of information, the Agency has proposed Standard Operating Procedures (SOPs) for estimating potential exposure. These SOPs have been widely criticized -- including by the EPA Scientific Advisory Panel (SAP)-- for being so conservative that they seriously overstate likely exposure. Examples are attached [see "Framework for Assessing Non-occupational. Non-dietary (Residential) Exposure to Pesticides"]. The SOPs have not yet been finalized, and the Agency recently delayed a second review by the SAP, even though the Agency must soon make decisions on food-use pesticides that have urban, residential uses. These SOPs will be used as part of the exposure evaluation. It seems unreasonable that the Agency

would use these exaggerated SOPs, which, when taken in the aggregate they so greatly overstate risk.

Wouldn't it be unfortunate if a food tolerance had to be reduced or removed due to lack of urban exposure data or use of overly conservative residential SOPs, which overstate potential exposure? Yet, this is likely to happen if the Agency does not seriously revise the SOPs to make them more realistic, identify data needed and call it in from companies, and await completion of the work of the industry task forces. As I understand, the Agency has given no indication that it intends to take any of these necessary actions to assure that it is making accurate exposure determinations.

Use of these pesticides is important in urban areas, and these products have been used safely for years, with little or no problems. RISE affiliated associations representing pesticide product users share our concerns as follows:

PROFESSIONAL LAWN CARE ASSOCIATION OF AMERICA (PLCAA).

PLCAA is an international association that promotes education, balanced legislation and public awareness of the environmental and aesthetic benefits of turf and ornamentals. PLCAA represents more than 1,200 lawn and landscape companies, industry supplies, government agencies, grounds managers, educators and students in the U.S., Canada and other countries.

More than 21 million U.S. households spent a record $16.8 billion on professional landscape/lawn/tree care services in 1998, according to a recently released Gallup survey. This represents a 2.2 billion increase on total spending over the previous year and a 32 percent increase in the average amount spent by each household on these professional services.

While these numbers are impressive, they only tell part of the green industry story. Turf and ornamentals are essential to a clean environment, are aesthetically pleasing, increase curb appeal and property value, provide a safe, cushioned play surface for children, and instill a sense of community and pride in our surroundings. In order to achieve the above benefits, one has to fight off literally thousands of insect species, plant diseases and weeds. In an age when people want instant results, pesticide are one of the few resources available to take care of these pests effectively. The loss of any pesticide product in a planned pest control strategy would reduce the array of products available to adequately manage pest problems and could cause more pesticide products to be used, resulting in increased total product use.

TURFGRASS PRODUCERS INTERNATIONAL (TPI).

TPI is a 32-year-old, international, not-for-profit trade association. Its more than 1,000 members in the U.S., Canada and 38 other countries preduce an estimated 80 percent of all cultivate turfgrass sod that is used on home lawns, golf courses, parks and sports fields, as well as near highways and other erosion-prone areas.

The 1997 Census of Agriculture reports that there are 1,784 sod farms in the U.S., cultivating approximately 302,930 acres and generating sales of $800,694,000. Since the 1992 Census, these figures have risen by 10.5 percent, 38.9 percent and 69.8 percent respectively. According to a recent Turfgrass Producers International survey, the typical sod farm in the U.S. is a 350 acre, family owned and operated operation that realizes more than 95 percent of its gross income from this single crop.

Today's consumers (both residential and professional) insist that the turfgrass sod they purchase be fully mature and totally free of weeds, insects and disease. Further, sod producers, and consumers alike, have all become more aware of the scientifically documented positive environmental and social advantages of properly produced installed and maintained turfgrass. The multiple benefits of turfgrass can only be achieved through the judicious use of pesticides that are carefully selected according to the specific pest, applied at proper time and in accordance with product labels. As profit-oriented firms, sod producers carefully monitor their use of pesticides to maximize efficacy and minimize overhead costs.

Widespread and well-grounded fears exist among all turfgrass sod producers and managers of turfed areas related to the potential loss of time-proven, cost-effective pesticides as a possible result of the EPA's current FQPA implementation methodology. Specifically, the turf producer concerns can be classified into four general areas:

1. Absent a transparent and scientifically based product review process, turf farmers may experience the immediate and unexpected loss of materials that do not have an equal or better replacement.

2. Pesticide registrants may determine that a turf-farm label cannot be justified as a result of FQPA implementation because the "minor use" will not justify the additional time and costs required to obtain a sod or turf-specific label.

3. Because turfgrass sod production is an agricultural activity, all pesticide products used on these farms must have Worker Protection Standards as part of the label. When WPS requirements are combined with FQPA concerns, products may be lost to pesticide applicators.

4. Absent a complete or expanding spectrum of pesticides, turf producers and managers may have no alternatives other than using greater and greater amounts of the limited number of remaining products. This result seems unintended under FQPA.

AMERICAN NURSERY AND LANDSCAPE ASSOCIATION (ANLA).

ANLA is a 125-year-old association representing 2,700 growers, landscape firms, retail garden centers and the 16,000 additional family farm members of State and regional nursery and landscape associations nationwide.

As with other agricultural crops, the growth and success of our industry depends on our ability to effectively manage insects, diseases and weeds. A pest infestation can quickly ruin a crop, with no recourse for the grower. If FQPA is implemented unfairly, ANLA members will lose effective and reliable pesticides that provide the ability to manage crops. Many pest control products currently being assessed by EPA are critical to Integrated Pest Management, environmentally friendly programs that control insects, weeds and disease through effective application of mechanical, cultural, biological and chemical tools.

GOLF COURSE SUPERINTENDENTS ASSOCIATION OF AMERICA (GCSAA).

Access to safe, efficient pesticides is vital to the golf course management industry. Ongoing training and education by the 20,000 member GCSAA ensures that golf course superintendents use pesticides safely.

Healthy golf course turfgrass provides many benefits to people and improves environmental quality for communities by providing green spaces. Golfers and others often do not realize the environmental benefits of well-maintained turfgrass.

Turfgrass reduces loss of topsoil from wind and water erosion; absorbs and filters rain and runoff water, recharging ground and surface water; captures and cleans runoff water from urban areas; improves the soil and restores damaged areas such as landfills and mining sites; improves air quality and moderates temperature; and reduces noise, glare and visual pollution. Golf course turfgrasses, trees, shrubs and water features create and enhance wildlife habitats, as well as enhance physical health while contributing to the community's economy.

The specialty pesticide industry is prepared to provide information to the EPA to support the continued use of its products and to help determine real overall exposure potential, but we need guidance and policy before decisions are made. On behalf of the industry, I urge this committee to continue to provide strong oversight on these issues.

I also urge each of you to support HR 1592, the Regulatory Fairness and Openness Act of 1999, introduced by Mr. Pombo. HR 1592 now has more than 140 cosponsors, including many other members of this committee. Of the measures introduced to strengthen FQPA implementation, we believe this legislation most fully serves the public interest. Among other provisions, this legislation provides for the use of actual data and scientifically sound information when reviewing food tolerances. This provision will help relieve the concern about the Agency's reliance on overly conservative assumptions about pesticide use and exposure, and will decrease the need for use of SOPs during the evaluation of residential pesticides.

I'll close by expressing my concern for how EPA plans to handle the "benefits" of public health pesticides. I believe the reduction of health threat risks to humans (the benefit) must be factored into the overall risk consideration, as a reduction in product risk, when EPA is evaluating food pesticides that also have public health uses. Failure to allow for the reduction of human health threats as part of the risk determination would undermine this section of FQPA, which is within the FIFRA portion of the law, and under oversight jurisdiction of this committee. I urge you to follow closely the Agency's policy development in this important area. I am including three documents as attachments to this testimony, which describe the value of public health pesticides:

1."FQPA and Public Health"; "The Problem with Pests," Dr. Michael F. Potter, University of Kentucky; "FQPA: A Public Health Perspective," Dr. Darrell Sumner, Wake Forest University

Thank you for allowing me the opportunity to express the concerns of this industry regarding FQPA implementation.

TESTIMONY OF RICHARD ROMINGER

Good morning Mr. Chairman and members of the subcommittee. I am pleased to appear before you today to discuss the U.S. Department of Agriculture's role in the implementation of the Food Quality Protection Act.

The U.S. Department of Agriculture has been engaged on a number of fronts relating to chemicals important to public health since the inception of the Food Quality Protection Act. FQPA requires the US Environmental Protection Agency to take into account aggregate exposure which could be characterized as the consideration of all non-occupational sources of exposure to pesticide residues in addition to those in food and water. FQPA also emphasizes consideration of childrens' special sensitivity and their exposure to pesticides. USDA has an active role working with EPA to assess the risk of both agricultural and public health uses of pesticides. The law also mandates that USDA work with EPA to develop alternative pest management strategies to pesticides which may be lost in the reregistration process. As you know, the FQPA Act requires USDA to conduct research/education to support the adoption of Integrated Pest Management (IPM). I will now update you on a number of these activities.

USDA'S ROLE IN THE REREGISTRATION OF PUBLIC HEALTH PESTICIDES

Of key public health concern for humans and livestock are mosquitoes and other biting insects. Thus far in the reregistration process, three organophosphates have been reviewed by USDA Office of Pest Management Policy and USDA's land grant partners which have implications on mosquito control. They are temephos, fenthion, and naled. The Department has commented on two other organophosphates for impact on fire ant control.

As a result of Tolerance Reassessment Advisory Committee discussions on the reregistration process, USDA and EPA have developed an intergovernmental review process to ensure that the revised organophosphate risk assessments are based on the best information available. Under this process, USDA reviews all pesticide risk assessments and, when necessary, work with EPA to develop risk mitigation and crop transition strategies. For all pesticides, in regards to non-agricultural uses of pesticides, USDA is required by FQPA to develop, with EPA and HHS, a list of major public health pests. This draft list will be sent out for public comment in the form of a Pesticide Registration Notice and is in the final stages of completion.

USDA receives a briefing of the overview of the revised risk assessment from EPA following their incorporation of public comments in phase 3. In this phase 4 review, USDA performs a headquarters review to provide any immediate feedback to EPA on use/usage data, the assumptions used, and on possible strategies and options for managing risk. Some reviews are more complex when food uses as well as mosquito and other public uses are registered. USDA also sends out the revised risk assessments to a number of land grant institutions and our own USDA Agricultural Research Service research facilities to take advantage of their expertise concerning critical public health uses of pesticides..

In regards to public health uses, USDA and EPA agree on a 15 day, 30 day or 45 day review time period for each chemical. USDA can call on EPA for clarifying briefings at any time during this process. By the end of the review period or shortly thereafter, USDA transits its comments to EPA. We both then work together to incorporate the comments into the assessment documents. The three mosquitocides I have previously mentioned are not yet at this stage.

Within a week following the incorporation of these additional comments, EPA announces the date of the Technical Briefing for sharing the risk findings to the public. The announcement will be made at least two weeks before the meeting to provide adequate advanced notice to stakeholders. At the briefing, if necessary, USDA will provide recommendations on possible risk management strategies and options. Stakeholders will have opportunity at the Technical Briefing to ask clarifying questions. The Technical Briefings for the first three mosquitocides are tentatively scheduled for September.

Concurrent with the technical briefing, revised risk assessments, which reflect comments incorporated from the intergovernmental review, are placed into the public docket. The public is given 60 days to comment on the revised risk assessment and any proposed mitigation measures.

During the reregistration process, when pesticides with public health importance are limited or canceled, EPA consults with the Department of Health and Human Services or USDA regarding the chemical's significance to that particular control program. For example, USDA's Animal and Plant Health Inspection Service (APHIS) maintains a list of pesticides needed for fire ant control. This year, USDA has provided feedback to EPA regarding two organophosphates used for fire ant control. We responded to EPA's consultation request and affirmed that the loss of the two organophosphates would have no impact on Animal and Plant Health Inspection Service operations for this important public health program.

Examples of Research into Alternative Pesticides

USDA ARS has a number of activities addressing pesticide alternatives and reduced pesticide usage for public health uses. In addition to IPM and precision targeting research to reduce pesticide usage in schools, homes, commercial buildings and other public places, USDA has conducted field releases of biological control agents for fire ants, mosquitoes and control of Lyme Disease. USDA ARS scientists worked cooperatively with a private entity to develop nontoxic strategies for eliminating cockroaches and their allergens by developing a vacuum device. USDA scientists have also developed a cockroach antigen detection system to enable pinpointing of contaminated, cockroach infested areas. Research with the University of South Florida is ongoing for the detection of cockroach antigens in flour.

USDA ARS has developed for the Department of Defense a reduced risk and spatially-based system that permits the rapid-determination of risk of transmission and a method to control the mosquito vector that does not rely on insecticides. Spatial risk assessment procedures were developed so that any pesticide application is avoided when risk of disease is zero or low. However, when risks are unacceptably high, this process identifies areas to target for mosquito source reduction (no pesticides), and the degree of suppression required to prevent or eliminate transmission. USDA is working with the Centers for Disease Control (CDC) to evaluate this IPM system in Puerto Rico where dengue is endemic.

Finally, in collaboration with the Air Force, USDA ARS is developing a software package to evaluate the threat of tick bites and transmission and chemical and nonchemical control options such as management of tick habitat or their hosts.

The U.S. Department of Agriculture will continue to pursue research into alternative pesticides, reduced risk approaches, and the reregistration of current pesticides to carry out the implementation of the Food Quality Protection Act. We look forward to continuing to work closely in partnership with our sister government agencies.

Thank you very much Mr. Chairman. I will be happy to answer any questions at this time.

Statement of Peter Robertson/James V. Aidala

Good morning Mr. Chairman and members of the subcommittee. I am pleased to appear before you today to continue our discussion of the Environmental Protection Agency's (EPA) implementation of the Food Quality Protection Act (FQPA). In my testimony presented several weeks ago, I provided you and your subcommittee with a brief summary of the Agency's latest progress in implementing this new law.

This hearing shifts the focus of the discussion from agricultural pesticide uses to non-agricultural pesticide uses. Non-agricultural pesticides include a wide array of product types that play an important role in today's society. Non-agricultural pesticides include public health pesticides that serve a significant role in protecting the public's health from disease vectors, such as mosquitoes that transmit malaria and encephalitis, ticks that cause Rocky Mountain Spotted Fever and Lyme Disease, cockroaches and rats. Non-agricultural pesticides also include antimicrobial pesticides such as sterilants used in hospitals and disinfectants used in restaurants. The last major group of non-agricultural pesticides includes residential uses. Millions of people rely on these pesticides for everything from bathroom sanitizers to lawn care. Although the focus of FQPA is primarily on the dietary concerns from pesticide-treated food, non-agricultural pesticide uses contribute to our overall exposure to pesticides. Exposure from non-agricultural pesticide products can be significant.

FQPA's requirement that EPA consider the aggregate risks of all non-occupational exposures to a pesticide when reviewing tolerances—including from agricultural and non-agricultural uses—has placed greater emphasis on evaluating exposure from non-agricultural uses. This provision has greatly accelerated the development and

use of new data and assessment methodologies for residential and other non-dietary exposures to more routinely incorporate consideration of these exposures in our risk assessments.

EPA'S APPROACH TO PUBLIC HEALTH PESTICIDES

Public health pesticides are defined in FQPA as "any minor use pesticide product registered for use and used predominantly in public health programs for vector control or for other recognized health protection uses, including the prevention or mitigation of viruses, bacteria or other microorganisms (other than viruses, bacteria, or other microorganisms on or in living man or other living animal) that pose a threat to public health." Because a pesticide can only qualify as a public health pesticide if it is a minor use pesticide, public health pesticides are afforded priority review and the other special considerations given to all minor use pesticides.

EPA is in the final stages of developing a Pesticide Registration notice (PR) outlining its policy with respect to public health pesticides. In addition to formalizing the list of public health pests required in FQPA, the PR notice will provide criteria for determining whether a pesticide use fits the statutory definition. One important criterion is that the pesticide is used in an organized vector control program. A public health pesticide is not simply a pesticide used against pests that have public health consequences; rather, a pesticide can only qualify as a public health pesticide if it is used predominantly in recognized public health programs for vector control or other public health purposes. For example, under this definition, an over-the-counter mosquito repellent would not be classified by the Agency as a "public health pesticide" even though it is used against a public health pest.

For any food use pesticide which also has public health uses, FQPA requires EPA to factor exposure from the public health use into our aggregate exposure assessments. There is concern by some public health professionals that this provision may lead to limits on some public health pesticide uses because registrants may choose to support more profitable food uses at the expense of public health uses.

When evaluating tolerances, consideration of the benefits of public health uses are limited to special circumstances, subject to the same restrictions in FQPA as all other pesticide uses. The important benefits of public health pesticides, however, would be considered by the Agency in determining how best to mitigate any unacceptable risks in order to bring aggregate exposures within safe levels. For example, if the aggregate risk of a pesticide were found to be unacceptable, EPA would consider the benefits associated with all the uses, and the availability of alternatives, when determining how to bring the risk down to an acceptable level.

EPA is sharing with DHHS all risk assessments for pesticides with public health uses at a stage well before any regulatory decisions may be made. Similar to our experience sharing preliminary risk assessments for food use pesticides with USDA, it is our hope that these early consultations will help us to significantly improve risk assessments for public health pesticide uses. To date, risk assessments for five public health OP insecticides have been shared with DHHS for comment. FQPA requires that EPA consult with DHHS and the Department of Agriculture (USDA) if the Agency were to conclude during this process that a non-food public health use may need to be limited or eliminated. Rather than relying solely on this requirement to ensure that public health uses are given appropriate consideration, EPA will continue to work with DHHS to improve risk assessments.

FQPA also included several other specific provisions that require EPA, DHHS, and USDA to work together when taking public health pesticides into consideration as we implement the law. EPA has selected a Public Health Coordinator to lead an internal Public Health Workgroup and to facilitate interagency communication and coordination. In particular, our Public Health Coordinator and internal workgroup have been working with the Office of Public Health and Science, the Center for Food Safety and Applied Nutrition, and the Centers for Disease Control to address the issues surrounding public health pesticides and how this group of products may be impacted by FQPA mandates. EPA and DHHS are in the beginning phases of designing a data development program for public health pesticides. We are working to put in place a Memorandum of Understanding to formalize this interagency cooperation to attain our common goals and are committed to maintaining a close, cooperative approach.

EPA'S APPROACH TO ESTIMATING RESIDENTIAL EXPOSURE

Background. The Agency uses term "residential exposure" to cover a broad array of use scenarios. These may include use in the home and garden; use in schools, parks, playgrounds, and public buildings; use in swimming pools; use on pets; and many other non-dietary, non-occupational exposures.

Because tolerance determinations did not explicitly include a detailed assessment of residential exposures prior to enactment of FQPA, EPA's databases and exposure assessment methodologies in this area are less robust than for dietary exposures. We have, however, been working for a number of years to improve our understanding of these issues, and the explicit FQPA mandate to consider aggregate exposures is resulting in rapid development of more sophisticated, refined approaches to residential exposure assessments by EPA, the pesticide industry, and commercial users of residential pesticides.

We have used a number of tools—including data call-in, voluntary cooperation with industry groups, and EPA supported research efforts—to improve our data and risk assessment methodologies. The Agency has developed and published for public comment new Standard Operating Procedures for estimating exposure to pesticides resulting from residential use. We issued a data call-in requesting residential exposure data from the Outdoor Residential Exposure Task Force. EPA's Office of Research and Development (ORD) has conducted and otherwise supported new research on residential exposure, particularly focusing on children's exposures. And we are employing new methodologies to assess activity patterns that can result in residential pesticide exposures.

All these activities are helping to greatly improve our assessments of residential and other non-dietary exposures, allowing the Agency to more rigorously account for these exposures as required in FQPA.

Standard Operating Procedures. As many of you are already aware, assessing the risks due to non-dietary, non-occupational exposure to pesticides was identified as one of the nine key science policy issues by the Tolerance Reassessment Advisory Committee. In response, EPA published for comment Standard Operating Procedures (SOPs) for estimating pesticide exposure for over 40 activity scenarios in residential and similar settings. EPA brought these draft exposure models before the FIFRA Scientific Advisory Panel in 1997 and plans to present its latest work to the Panel this coming September. Our latest work will present new analysis of recent studies relating to key post application variables including percent dislodgeability of pesticides from turf, indoor surfaces and pets; dermal exposure methods; methods for estimating non-dietary ingestion; pesticide drift and contaminated house dust.

EPA is currently using these "Residential SOPs" to produce screening level assessments of residential pesticide exposure, using information derived from the pesticide labeling and other generally available data. Thus, SOPs are equally applicable to new products and products that are already in the marketplace. The SOPs represent conservative or screening level estimates of exposure and are used to identify those instances where there may be a potential for concern. If the screening assessments indicate that the risks from residential exposures is within acceptable limits, no further analysis is required. In the event, however, that the SOPs estimate potential exposures of concern, the Agency may seek additional information, determined on a case-by-case basis, to produce a more realistic estimate.

Exposure Methodology. In estimating residential exposures for a given use scenario, consideration of two general factors is necessary: the amount of pesticide residues present that a person could come in contact with, and the behavior or "activity patterns" that could result in exposure.

To determine the amount of pesticide residues that may be available, EPA uses data on "dislodgeable residues" (the portion of the applied pesticide that can be physically removed during an activity) developed by pesticide registrants. This data, however, may not be available for all pesticides used in and around the home. In some cases, EPA may use assumptions, based on existing data, to estimate higher end exposures. For example, the Agency assumes that 20 percent of the applied pesticide can be removed from a treated lawn, and 50 percent of a pesticide can be removed from an indoor surface.

To reduce the need for such estimates, EPA issued a data call-in requesting residential exposure data from all registrants of lawn use chemicals. The Outdoor Residential Exposure Task Force, a consortium of companies which produce such pesticides, was formed to satisfy the data call-in. The 117 pesticides subject to this data call-in were divided into two groups based on their toxicity or usage. Data on chemicals in group I (chemicals of greater concern) are due by October 30, 1999. Data on group II (chemicals of less concern) are due by October 29, 2000. EPA will use these data to refine both pathway specific and aggregate exposure assessments for these pesticides.

In characterizing activity patterns, the Agency can use data from certain agricultural use settings to estimate exposures from similar residential activities. For example, working in a home garden or lawn is similar to related agricultural activities. Data derived from fieldworker studies, then, can be extrapolated to help estimate exposure from these related residential activities.

The Agency uses other methods for estimating post-application exposures from other residential activity patterns. For example, EPA is using a method developed by the California Department of Pesticide Regulation that uses the Jazzercise routine to predict exposures from certain residential activity patterns. Also, over the past few years, EPA has compiled a large database containing data on human activities in and around the home. This should prove useful in estimating pesticide exposures with increased confidence.

Research. Because of FQPA's focus on the safety of infants and children, EPA is most concerned about children's exposures to pesticides in their homes, schools, daycare settings, and outdoor play areas. In addition to developing SOPs for estimating infants' and children's exposures to pesticides in these settings, EPA is conducting or otherwise supporting research to measure transfer of pesticide residues from residential surfaces to a child's body. Research in this area focuses on improving our understanding of exposures that infants and children receive in residential "microenvironments." Research objectives include (1) developing and demonstrating measurement methods and protocols for dislodgeable contaminant residues from lawns and indoor surfaces; (2) developing and demonstrating measurement methods to characterize residential dermal exposure and dermal-oral ingestion of contaminants, and (3) developing multipathway exposure-dose models to represent these exposures. Exposure measurement research is focusing on characterizing long-term exposures, biological markers of exposure, and associated activity patterns for two hundred fifty young children in both daycare and home settings. Another study is focused on residential pesticides exposures of children between the ages of three and twelve in Minnesota. EPA's ORD is also supporting research on transfer of residues from pets treated with pesticides. In addition, ORD's National Human Exposure Assessment Survey program (NHEXAS) is gathering valuable information on the distribution of human exposures to multiple chemicals via multiple pathways. In addition to ORD's exposure research activities, EPA can often adapt data from other sources in its residential exposure assessments. The Agency is examining use of exposure data from turf uses, spray drift studies and farm worker children studies. While not direct residential uses, analysis of these exposure scenarios may provide some important clues to assessing exposure in the residential environment.

FQPA has also challenged the research community. Behavioral studies and environmental exposure are newly emerging sciences within academia. Industry is also taking an active role. EPA is working closely with companies, users, and university researchers to design and implement appropriate and cost effective methods for gathering data for evaluating residential pesticides exposure. Not surprisingly, the pesticide chemical industry is committing substantial resources to this issue. Information acquired from research or from studies submitted in support of registration will help significantly improve the understanding of which exposure scenarios are of most concern.

Making Regulatory Decisions. The use of available, scientifically sound data is essential for making any regulatory decision, including those that involve residential uses. Reliable data from all available sources (including modeling, direct measurement, and peer-reviewed literature studies) are used in an assessment. Where additional data may be useful in refining risk assessments, EPA will address on a case-by-case basis whether such data are reasonably required to support continuation of a tolerance.

Where a risk assessment indicates a potential concern, the Agency is conducting sensitivity analyses—revisiting critical assumptions and data to determine what impact they may have on the risk determination. If these analyses suggest that key assumptions appear to lead to significant overestimates of risk, EPA may defer a decision until appropriate data are developed to refine the risk estimate. Conversely, if the sensitivity analysis suggests that assumptions are not critical to the assessment, EPA would be reasonably confident that even with the more refined data, mitigation measures may still be needed. Because of the Agency's responsibility to take prompt action to mitigate risk, EPA believes it would be inappropriate to delay decisions where available data are sufficient to reach a decision.

Residential Exposure to the OPsBecause FQPA mandates priority reassessment of those pesticides that appear to pose the greatest risk, EPA has been focusing on evaluating exposures to and completing risk assessments of the organophosphate (OP) pesticides. Currently there are 17 OP pesticides with major residential uses.

We are fortunate that all 17 OPs with a potential for residential exposure have some level of actual data on which to base our assessments. For residential applicator exposure scenarios to the OPs (i.e., the homeowner who is applying the pesticide), the Agency is reassessing previous (i.e., pre-FQPA) conclusions with respect to use directions and the type of equipment used. For example, a homeowner, when applying an organophosphate insecticide may use a lawn spreader, hand held shak-

er can, or a sprayer attached to a garden hose. Each of these three methods of application results in different exposures.

In addition to the reassessments underway, EPA has also given priority to registering new, safer alternatives to existing pesticide uses that may pose greater risks. A good example of this is the recent registration of a new active ingredient for insect control. On June 30, EPA granted a registration for N-Methylneodecanamide (MNDA). MNDA will be used in the formulation of multi-purpose cleaner/insect repellent products to repel cockroaches and ants on household floors, walls, bathrooms, and other non-food contact surfaces. By placing a high priority on the registrations of these types of chemicals, we hope to stimulate development and registration of viable OP alternatives.

Antimicrobial Pesticides. As I stated earlier in my testimony, non-agricultural uses also include some very important antimicrobial uses. FQPA fundamentally changed the way and rate at which EPA registers antimicrobials. FQPA reformed the antimicrobial registration process, with the goal of achieving significantly shorter EPA review times. It was in response to this mandate that EPA established the Antimicrobial Division (AD) within the Office of Pesticide Programs. In the past 3 years, AD has achieved a 98 percent reduction of backlog actions and has met all registration deadlines for submissions filed since November of 1996. In addition, the Antimicrobial Regulation Technical Corrections Act of 1998 (ARTCA; P.L. 105–324) established EPA's jurisdiction over sanitizers used on semi-permanent and permanent food contact surfaces.

It is without question that non-agricultural pesticides play an important role—whether it be to control dandelions in the front yard, fleas on the dog, or disease vectors. However, along with these benefits comes exposures to these pesticides. These exposure pathways can be significant in some cases. Household pesticide uses (including lawn and garden) account for 17 percent of all pesticides sold in the United States. Non-agricultural professional sales, which include institutional uses (schools), and commercial uses (public buildings, golf courses), account for 13 percent ($1.4 billion) of total U.S. sales. And a 1995 study conducted by the Centers for Disease Control and Prevention found a metabolite of a common household insecticide in the urine of 82 percent of the people monitored. As these numbers illustrate, food is by no means the only route of exposure.

The provisions in FQPA ensure protections not only from pesticides in our food, but also from pesticides in the air we breathe and the things we touch. And FQPA placed greater emphasis on non-agricultural pesticides. We are gathering new data and developing new methodologies in collaboration with pesticide users and producers and with our other government partners. By working in partnerships, we can meet the FQPA challenges and realize the better protections we all desire for our families and our children.

Thank you very much Mr. Chairman. I will be happy to answer any questions at this time.

STATEMENT OF JEROME GODDARD

CURRENT STATUS OF VECTOR-BORNE DISEASES

Infectious diseases are making a strong comeback after a lull in the years immediately following World War II. The ability of microbes to adapt to host immune responses and intense pressure from antibiotic use, combined with societal changes, have contributed to a resurgence of many infectious diseases. In addition, there are now several "new" diseases, including Legionnaires' disease, Lyme Disease, ehrlichiosis, toxic shock syndrome, and Ebola hemorrhagic fever. In just the last 2 or 3 years we have seen the appearance of a virulent strain of avian influenza that attacks humans, a human variant of "mad cow" disease, and new drug-resistant forms of *Staphlococcus aureus*. These new or emerging infectious diseases have raised considerable concern about the possibility of widespread and possibly devastating disease epidemics.

Many of these emerging or reemerging infectious diseases are vector-borne. Since 1975, dengue fever has surfaced in significant outbreaks in more than 100 countries. The more insidious form of the disease, dengue hemorrhagic fever (DHF) and dengue shock syndrome (DSS) with internal bleeding and shock mainly affect children under age 15, and about 5 percent of the cases result in death. In the 1970's only nine countries had experienced DHF outbreaks; to date 44 countries have had DHF cases or epidemics. The malaria situation is worsening as well. There are now an estimated 300 to 500 million cases of malaria each year with 1 to 2 million deaths (mostly children). Several factors are responsible for the resurgence of malaria: (1)

insecticide resistance in the vector mosquitoes, (2) drug resistance in the malaria parasite, (3) inadequate funding for malaria control, (4) civil strife with accompanying refugee problems, and (5) increased travel by non-immune expatriates. For example, 2 to 3 million new cases of malaria have been reported each year recently in Afghanistan as a result of disruption of control, civil disturbance, and migration. Plague is also reemerging. In the U.S. there has been an increasing number of States reporting cases and an eastward movement in human case occurrence toward the 100th meridian. The incidence of cutaneous leishmaniasis is increasing in Central and South America because of road building, mining, oil exploration, deforestation, and establishment of communities adjacent to primary forest. Lyme Disease, almost unheard of in 1979, is now the number one tick-borne disease in the U.S. with approximately 12,000 cases reported each year. Other tick-borne diseases such as babesiosis and ehrlichiosis are also emerging. Several new Babesia species infecting humans have been found. Likewise, there are at least two Ehrlichia species in the U.S. that produce spotted-fever like illnesses. Others will likely be found.

It could be argued that at least some of the increase in vector-borne disease is due to increased recognition and reporting. Specific disease recognition is certainly made easier by novel technologies such as PCR. However, societal changes such as population increases, ecological and environmental changes, and especially suburbanization (building homes in tracts of forested lands) are contributing to an increase in incidence of many of these vector-borne diseases.

Cause for Future Concern

It appears that humans are in a precarious situation. The entire ecosystem—including plant and animal life on earth—is being affected by humanity. Humans once lived in far-removed, relatively isolated groups. Now we are all essentially one large community. Further, things such as population increases, building cities in/near jungles, and widespread and frequent air travel are providing the opportunity for a great plague. A person hiking in the Amazon jungles today might be in New York City tomorrow and bring back with him some exotic disease. Should one or more new "emerging" vector-borne diseases begin to spread, control of the epidemic would be difficult. If the disease agent is a virus, conventional antibiotics are of little help in treatment. The only way to stop a viral vector-borne illness is to kill the vectors to a low enough level to interrupt virus transmission. If the vector is a flying insect, control of an epidemic is even harder. Compounding all of this, many insect species are resistant to many of the insecticides used to control them.

The Need for Pesticides

Appendix I is an excellent description of how societal and ecologic changes in the future necessitate pesticide use. Pesticides are indeed poisons. After all, they are designed to kill things. But the EPA registration process, requiring many years of product testing and review, helps ensure that EPA-registered products are safe when used according to their label directions. Millions of dollars are invested in testing pesticide products—before they ever reach the consumer—for their relative safety to humans and the environment. Prospective pesticides are tested for harmful effects to adults, children, the unborn, as well as the environment. Some people claim that pesticides are ruining the environment and causing widespread disease (such as cancer) in the human population. But where is the evidence? Wildlife is rebounding after years of decline. There are more deer and wild turkeys in the U.S. now than at the turn of the century. Raptors are back. People are living longer and longer. We must be doing something right.

In my opinion, pesticides are extremely important to human survival. They are essentially "environmental medicines" to correct insect imbalances. Not only are they needed for crop protection, but as public health tools. We need a wide array of pesticides to combat any vector-borne diseases that may arise, or any re-emergence of existing diseases (such as malaria, dengue, etc.). Certainly, integrated pest management and other strategies to reduce pesticide use are in order, but in many cases insect populations explode and are unmanageable by non-chemical methods. We must have pesticides readily available for use. Not only do we need pesticides, we need a wide variety of them with various labeled uses. Even the "older" generation pesticides—such as organophosphates (OPs)— are needed. Pesticide resistance is developing to many of the newer synthetic pyrethroid compounds; keeping the OPs gives pest controllers, farmers, and vector control personnel another option in managing/preventing insecticide resistance. Furthermore, registrations for many pesticide uses are considerod "minor" by the EPA and chemical companies, and thus, not much attention is paid to them. In fact, many of these minor uses are

being dropped totally. This concerns me. We need all legitimate pesticide registrations to remain in effect as part of our repetoire of weapons against insect pests.

APPENDIX I

Excerpted from Knipling, EF, The Basic Principles of Insect Population Suppression and Management, USDA Agriculture Handbook No. 512, 1979.

"The increasing numbers of people (in the future) will need more food and other agricultural products. People will also expect maximum freedom from insect annoyance, or from threats to their health that certain kinds of insects cause. Thus, society will demand even more rigid insect-control practices in the future than it does today.

We must also remember that effective control of insects will probably become increasingly difficult in the years ahead. More land will have to go into cultivation or be used for livestock production. More space will be required for homes, industrial complexes, highways, and other needs. Tnis further disruption of the environment from a physical standpoint will mean greater disturbance to the ecology of the environment than already exists. This, in turn, will make managing certain major pests increasingly difficult because we will have less help from the natural biotic agents, which even in a natural balance often fall short of the degree of control we desire but which are nevertheless, essential for successful control and management of most insect pests.

In addition to the increasing disruption of man's environment because of physical changes, the continuing movement, accidental or otherwise, of thousands of plants, insects, and other biological organisms from one area to another has perhaps created biological imbalances comparable to physical changes in their impact on the ecology of our agricultural environment.

The many advantages of insecticidal chemicals and the untold benefits that have and will continue to accrue from their use must not be disregarded in these days of growing public concern and severe criticism directed against those who use or advocate the use of insecticidal chemicals of the type now available.

TESTIMONY OF RALPH ENGEL

Thank you Mr. Chairman and members of the subcommittee and good afternoon. My name is Ralph Engel. I am president of the Chemical Specialties Manufacturers Association.

CSMA has a membership of some 400 companies who manufacture, formulate, distribute and sell many types of consumer, industrial and institutional products including non-agricultural pesticides.

A significant number of our members' preducts have pesticidal claims and are, therefore, subject to EPA jurisdiction pursuant to the requirements of the Federal Insecticide, Fungicide, and Rodenticide Act—FIFRA.

In 1996, Congress passed the Food Quality Protection Act (FQPA), which amended FIFRA. Among FQPA provisions were reforms to the antimicrobial registration process, including the establishment of performance goals for registration of antimicrobial pesticides which established registration timelines. It also established a statutory definition for these products. Mr. Chairman, I am pleased to state that the agency has made significant improvements in the overall registration of these products.

Unfortunately, other sections of FQPA create uncertainty in the system of registering pesticides for non-agricultural pesticides. Our industry is concerned that EPA appears to be bent on implementation of the FQPA based on an arbitrary deadline that may lead to decisions based on faulty risk assumptions rather than on sound data. Additionally, industry is concerned with the lack of sound science, in that risk management decisions are being made while many of the FQPA science policies are not finalized and remain in draft form and/or have not been issued for public review and comment. This may result in the loss of products that are important to consumers and institutions and lead to potentially significant public health consequences. If the provisions of FQPA are not properly implemented, many products that benefit and protect consumers will be lost. To avoid this, we must have regulations based on sound science and reliable data based on real life assumptions and risks.

I appreciate the opportunity to testify before the subcommittee today. My testimony focuses on four areas:

First an overview of the benefits of non-agricultural pesticides and of public acceptance of these products;

Second, the implementation of the Food Quality Protection Act and the potential loss of some of these valuable residential pesticide products that it may cause;

Third, I will report on the industry's progress in generating real wold data and the need for sound science and reliable information; and

Finally, I will discuss the implementation of the antimicrobial reform provisions of FQPA.

Benefits of non-agricultural/consumer protection health benefit products

CSMA defines the general-use, residential or non-agricultural pesticide products we represent as Consumer Protection and Health Benefit Products. This definition includes, among other things, any disinfectant, sanitizer, germicide, insecticide, repellent, rodenticide and any pesticide labeled for use on pets as well as any pesticide labeled for use in areas "in or around household premises."

Unfortunately, the term "pesticide" has a visceral negative connotation for the public. Moreover, the term "pesticide" focuses only on the function of the products, completely ignoring the many benefits derived from the use of these products.

Life today, would be quite different without the use of pesticides—disease would run rampant, food would be scarce and certain areas of this country would be uninhabitable due to pests such as mosquitoes, ticks and rodents.

There are significant threats to consumer health that can be achieved by the use of Consumer Protection and Health Benefit Products. For example:

Disinfectant products are used by millions of people every day to keep kitchens and bathrooms clean and help prevent the spread of germs. These products are vitally important to protect health in nursing homes, hospitals, hospices and other health care facilities. (See attachment A)

Proper use of disinfectants and sanitizers in dairy farms and food preparation areas can help aid food safety and sanitation efforts by protecting against Salmonella, E.coli, and other bacterial contamination.

Disinfectant products can be used to eliminate mold that can also cause severe health problems for children, adults, the elderly and those with compromised immune systems. Mold has also been found to be a major contributor to poor indoor air quality and associated physical illness.

Pet products are vital to keeping both families and pets healthy and comfortable by protecting them from disease-carrying fleas and ticks. (See attachment B)

Insect repellents are critical to protecting the public against tick-borne diseases that have become a rapidly emerging public health threat. For example, the annual reported number of Lyme Disease cases increased 25-fold between 1982 and 1997, with a cumulative total of more than 103,000 cases reported in that period. Recent reports suggest that the threat of Lyme Disease this summer may be greater than ever. Moreover, several new tick-borne diseases that can potentially cause death have recently been identified. (See attachment C)

Additionally, insect repellents are essential to public protection from mosquitoes. Mosquitoes can transmit serious, potentially fatal diseases such as encephalitis, dengue fever and malaria, all of which occur in the US. Various parasitic diseases once considered exotic in the U.S. including mosquito-borne diseases, are emerging or re-emerging as public health threats.(See Attachment D)

Insect and rodent control products protect against the transmission of disease by these pests. For example, cockroaches have been found to carry hundreds of different types of bacteria, and rodents can transmit many diseases, including the potentially fatal Hantavirus.

The health threat posed by rodents and insects should not be minimized. Our own capital city has a serious rodent problem, which could, if not controlled, put the citizens of the District of Columbia at risk. According to the US EPA, in the United States each year, rats bite approximately 14,000 people.

According to the American Association of Poison Control Centers, approximately 6,000 people each year are treated for insect stings in health care facilities. In fact up to five percent of the US population can have a severe, allergic, life-threatening reaction known as anaphylaxis in response to insect stings.

Recent research has found that cockroach allergens are a leading trigger for asthma among inner-city children. According to the American Lung Association, there are 15 million people with asthma in the United States. Nearly one-third of them are children under 18 years of age. Asthma is the most prevalent chronic illness of children and the greatest incidence of this condition occurs among inner city children. A May 1997 study published in the New England Journal of Medicine found that children allergic to cockroach allergens and heavily exposed to the insects at home were three times more likely to be hospitalized than other asthmatic youth.

Recently, the President's Task Force on Environmental Health Risks to Children cited these studies and noted that: "the role of indoor allergens on exacerbation of asthma, different allergens, such as those associated with cockroaches, dust mites,

and mold, have been implicated in different cities... Reducing exposures of children with asthma to airborne allergens and pollutants will reduce the health burden of asthma and significantly improve their quality of life.

CSMA commissioned survey of California residents. In November 1998, CSMA contracted with a respected public opinion research firm, Market Strategies Inc., to conduct a telephone survey of 1,300 California residents about their concerns relating to health threats posed by insects, rodents and microbial contamination. The survey was conduced in accordance with the demographic profile of the state of California. We have attached a copy of the survey results into the hearing record. (See Attachment E)

We undertook this survey because we believe that the public has significant concerns regarding the health threats posed by pests. We found that 78 percent of respondents believe that society should do more to protect children from insect and rodent pests. Forty seven percent of survey respondents believe that California children are becoming sick due to contact with insects and rodents. And 64 percent of all respondents affirmed that household pesticide products are crucial for keeping their homes free from insects and rodents.

These public health benefits should be fully considered and weighed heavily during the regulatory and decision making implementation of FQPA.

Public Health Pests. In addition, Congress saw the need to protect against public health pests and, therefore, Section 28 of FIFRA was amended to direct the EPA Administrator in coordination with the Secretary of Agriculture and the Secretary of Health and Human Services to identify pests of significant public health importance and to implement special programs to facilitate the use of chemical, biological and other methods to control such pests: "(d) PUBLIC HEALTH PESTS.—The Administrator, in coordination with the Secretary of Agriculture and the Secretary of Health and Human Services, shall identify pests of significant public health importance and, in coordination with the Public Health Service, develop and implement programs to improve and facilitate the safe and necessary use of chemical, biological, and other methods to combat and control such pests of public health importance."

We support and encourage the EPA in its efforts to establish programs aimed at combating pests of public health importance.

Implementation of FQPA and potential loss of valuable residential or non-agricultural pesticide products. Science-based implementation of FQPA requires both time and a process that will accommodate the data and assessment methods that industry is working to develop in cooperation with EPA.

As a result of a memo issued by Vice President Gore to EPA and USDA regarding the implementation of the FQPA, the Tolerance Reassessment Advisory Committee—TRAC—was formed. TRAC was composed of representatives from the environmental/consumer/farmworker perspective, agriculture/farmer representatives, pesticide companies and trade associations, NACEPT/SAP representatives, and academia. CSMA is on the committee and represents the non-agricultural pesticide industry.

TRAC is not a technical panel, but rather is charged with developing and recommending policy and strategy issues for FQPA implementation. To establish an overall reference framework, TRAC began focusing on organophosphates at the request of EPA.

FQPA directs EPA to consider both aggregate exposure and cumulative effect of pesticides in the registration process. As a result, TRAC has focused on the development of nine science policies including two that are of extreme importance to CSMA: residential exposure and aggregate risk.

Residential Exposure. EPA intends to refine its exposure models based on data that the pesticide industry is generating as well as other reliable data. In the meantime, the Agency will use a combination of relevant data and model estimates to assess residential exposure.

CSMA has a number of concerns with EPA's Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments. These are:

EPA SOPs for residential exposure assessment do not currently utilize/incorporate all publicly available scientific literature. This literature would most certainly displace some of the overly conservative "default assumptions." Further, in the absence of a careful and complete review of existing literature, EPA cannot accurately determine data gaps. Where data gaps do exist, due to the incomplete and draft status of the Series 875 (Group B Post-Application Exposure Monitoring Test Guidelines), adequate guidance is not available for development efforts. Many of the test methods in the Series 875 still need to be validated and peer reviewed. In essence then, development of studies cannot begin until these guidelines are finalized.

To overcome the problem of compounding conservative estimates, EPA needs to address the utilization of probabilistic versions of the "models" being proposed for use in addressing potential residential exposures. Probabilistic (e.g., Monte Carlo) techniques are necessary for characterizing the variability associated with many of the key aspects of residential exposures, e.g., time-activity patterns, consumer and professional product use/usage practices, exposure monitoring data, physiological and residential exposure factors, etc.

The residential modeling approach being developed needs to be transparent with respect to the assumptions and algorithms used, particularly given the "evolutionary process" that is occurring as new data and information become available and are incorporated into the methods/models. To facilitate this process, a more articulate presentation of the overall modeling process and the various elements that contribute should be developed. The current draft SOPs do not sufficiently explain the source and rationale of the default assumptions.

Product label and use information is one of the key elements in the residential exposure assessment process (both aggregate and cumulative). The utility of this information and associated publicly available sources should be more clearly described in the EPA SOPs and/or the 875 Series guidelines.

The Agency should use the revised SOPs only as a first-tier screen to determine whether more data and/or higher-tier exposure assessments are needed. The SOPs should not be used in aggregate risk assessments or to show that a pesticide use causes a certain actual amount of exposure or poses a certain level of risk that warrants action against a registration, registration application or tolerance.

We have attached a copy of the comments CSMA submitted on March 5, 1999 regarding the SOPs. (See attachment F)

CSMA does not believe EPA should make final assessments prior to availability of data. Interim assessments may be made with final decisions contingent on the outcome of the data being developed. If final decisions are made prior to availability of data, valuable non-agricultural pesticide products could be lost.

Aggregate Exposure. Aggregate exposure to a pesticide can occur by multiple routes: ingestion, inhalation, and/or dermal absorption and from multiple sources including residential, pet and lawn care uses. EPA has developed models for estimating exposures but these models are based on unrealistic assumptions and appear to overestimate the actual exposure to these products.

Thus, when aggregated assumptions for a given product are too conservative, an exaggerated exposure scenario can result. If final decisions are made prior to availability of data, valuable non-agricultural pesticide products may be lost. That is why it is so important to base decisions on good data.

Risk Cup Concerns. In addition, we are also concerned about allocation of the so-called "risk cup" and the need to preserve residential pesticide uses which may be forced out by other uses. Non-agricultural pesticide products may be lost if faulty risk assumptions are allowed to cause the "risk cup" to overflow. The "risk cup" is a mechanism for calculating permissible total exposure to an active ingredient. It is likely that these uses would be focused in the agricultural arena, not the non-agricultural sector. If the cup overflows, active ingredient manufacturers would be forced to choose where they would market the active ingredient in question. In some instances, the dietary exposure will completely fill the risk cup leaving little or no space for non-agricultural uses. Therefore, the agency needs to establish a process to ensure that non-agricultural pesticides are not forced from of the risk cup.

There is ample authority under Section 25(a)(1) of FIFRA for the Agency to take into account differences in concepts and usage between various classes of pesticides, including public health pesticides, and the differences in environmental risks and appropriate data between agricultural and nonagricultural pesticides:

"(1) Regulations. The Administrator is authorized in accordance with the procedure described in paragraph (2), to prescribe regulations to carry out the provisions of the act. Such regulations shall take into account the difference in concept and usage between various classes of pesticides, including public health pesticides, and differences in environmental risk and the appropriate data for evaluating such risk between agricultural, nonagricultural, and public health pesticides."

Therefore, it is appropriate for EPA to address both agricultural and non-agricultural pesticides separately in the implementation of the requirements of FQPA. The agency needs to ensure that these valuable Consumer Protection Health Benefit Products are not lost.

Data Gathering. In order to respond to FQPA issues related to non-agricultural pesticides, CSMA has established two joint ventures. The first one being the Indoor Residential Exposure Joint Venture (IREJV). This is a group of companies that manufacture and formulate pesticide products for residential and commercial markets. The IREJV is creating a database relating to product use that may be incor-

porated in modeling tools that are being designed to create exposure and risk assessments for pesticides products. The IREJV has undertaken a program consisting of two comprehensive projects, a label data entry system and an unprecedented major national consumer use survey.

The beta version of the label data entry system is complete and currently being tested. The database combines currently available information from several sources including EPA-maintained databases, the National Home and Garden Pesticide Use Survey and company-specific product label information. This important tool will allow assimilation of information on product labels such as application rates, method of application and pests treated.

The IREJV is working with a Regulatory Advisory Committee, including participants from the EPA, Cal EPA, and Health Canada, that will ensure that appropriate decisions are made regarding data needs and regulatory requirements.

The second joint venture is the recently formed Antimicrobial Exposure Joint Venture (AEJV) which also operates under CSMA auspices and consists of manufacturers and formulators of antimicrobials. The AEJV is currently collecting information and developing a viable program to address necessary antimicrobial data requirements.

Antimicrobial Reform Provisions of FQPA. As noted earlier, FQPA Subtitle B, Antimicrobial Pesticide Registration Reform, directs EPA to change the manner in which it regulates antimicrobial pesticides. Some of the key provisions include:

Statutory goals for making decisions on different categories of applications for registration of antimicrobial pesticides and a requirement to report to Congress annually on EPA's success in meeting the goals.

Statutory deadlines for issuance of regulations to streamline the registration process in order to meet the goal timelines of decisions on antimicrobial registration actions.

A direction to work with States to eliminate duplicative, burdensome regulation.

CSMA has been working closely with the Antimicrobial Division of EPA since the passage of FQPA. According to the statute, the Agency was to have proposed a rule in May 1997 and issued a final rule in May 1998. Neither of these timelines has been met, however CSMA has had the opportunity to review and comment on two drafts of the pre-proposed rule.

Although the rule has yet to be proposed, the Agency is currently operating under the goal timelines for processing registration actions that are delineated in the statute. CSMA anxiously awaits publication of the procedural rule, which, we understand, is scheduled to be proposed in the fall.

Data Coordination. Additionally, CSMA has always sought to maximize the coordination between State pesticide regulatory agencies and the US EPA. Fundamentally, the elimination of redundancies and the coordination of scientific reviews minimize both the cost to government and the cost to registrants. Moreover, coordination provides opportunity to streamline and make more efficient the regulatory process. The Congress concurred with this position and as part of the FQPA, (FIFRA 3 (c) (2)(B) (viii), Congress empowered the EPA with the authority, to the maximum extent practicable, to "coordinate data requirements, test protocols, timetables and standards of review." In this provision Congress noted the need to "reduce burdens and redundancy caused to the registrant by multiple requirements." In addition, the Administrator is directed to "develop a process to identify and assist in alleviating future disparities between Federal and State data requirements."

The experience of CSMA members is that procedural impediments at US EPA have resulted in a lack of coordination and an absence of data sharing between US EPA and State pesticide agencies. In order to fully implement this provision, we encourage the EPA to implement a clear procedure to facilitate this process, whereby registrants can authorize and direct EPA to share data reviews with State agencies. The lack of coordination to date should make clear the need for such a procedure to be implemented in order for registrants to avail themselves of the relief provided for in this provision of FQPA.

In conclusion, the implementation of the Food Quality Protection Act must be based on good data sound science. Non-agricultural pesticides or Consumer Protection and Health Benefit Products provide important benefits to our society, beyond the aesthetic benefits of keeping our surroundings clean, protected and free of pests.

Our products play an important role in limiting the spread of germs and are essential for controlling pests such as fleas, ticks, roaches, mosquitoes and rodents that can spread human illnesses.

Should the Food Quality Protection Act be enacted on the basis of faulty risk assumptions rather than on real world data, the likelihood is that some products that are vital to the protection of public health may be lost. The result would be detrimental to the, consumer, industrial, and institutional users of these products.

Industry is working with EPA to provide the needed data. We need your help to make sure there is time to do the work. We believe it is more important for the agency to make the right decisions based on good data and sound science than it is to meet any arbitrary deadlines.

We urge the subcommittee to instruct EPA to allow sufficient time to: gather residential exposure and aggregate risk data, permit data generation under appropriate study guidelines and protocols, and most importantly, to establish a process to ensure that non-agricultural pesticides are not forced from the risk cup arbitrarily.

On behalf of CSMA, I appreciate the opportunity to appear today to discuss the many benefits of non-agricultural pesticides and implementation issues related to FQPA.

STATEMENT OF WILLIAM LOVELADY

My name is Bill Lovelady. I am a cotton farmer from Tornillo, Texas near El Paso. As a farmer, I take seriously my role as a steward of our land and natural resources. I am also a father. And I want you to know that my kids eat lots of safe and nutritious American grown fruits and vegetables.

Thank you, Mr. Chairman, for your leadership and interest in this important issue of the Food Quality Protection Act (FQPA) implementation. Thank you also for the opportunity to speak, once again, on behalf of the National Cotton Council (NCC) before your subcommittee. I have testified before this subcommittee in the past. This time I do so with a great deal of concern and disappointment in the recent actions taken by the U.S. Environmental Protection Agency (EPA). I must be honest, Mr. Chairman, the NCC normally tries to be courteous and diplomatic in these types of issues. However, considering the haste and timing of these decisions, it is blatantly obvious that EPA has abandoned sound science and has replaced it with political science. It is clear that, with a presidential election upon us next year, EPA is bending to the demands of the environmental activists.

I am a former president of the NCC and the NCC representative on the Tolerance Reassessment Advisory Committee (TRAC). FQPA passed unanimously through both chambers of Congress and was signed into law 3 years ago to this date. For almost 2 years, there was a deafening silence from both the EPA and the agricultural community on this issue. In early 1998, an internal EPA memo was leaked. This memo suggested that, as one of several options, EPA might cancel all organophosphates (OP's) by May 15. The prospect of such a cancellation and the importance of the OP's to agricultural production were enough to energize the ag community to organize and become vocal. The agricultural community knew that EPA did not have the data or the methodologies needed to implement the new safety standards of FQPA particularly the aggregate and cumulative risk assessments. They feared that, in the absence of such science, EPA would proceed with implementation using conservative default assumptions and that crop protection tools would be unnecessarily eliminated. Responding to this outcry, Mr. Stenholm and Berry consulted with Vice President Gore. The Vice President issued a memo in April directing EPA and USDA to work together on FQPA implementation and that they were to be guided by four principles: sound science, transparency, stakeholder input, and transition.

The outcome of that memo was the formation of the TRAC process. The TRAC has met on six different occasions. Its final meeting is tentatively scheduled for some time in October. Although there has been some criticism of the process, my personal opinion is that TRAC has been very useful and has made significant progress for several reasons. First, the TRAC has been a useful means for producers and other interested parties to participate in FQPA implementation and to voice their concerns. Second, the TRAC meetings have also resulted in an increased role for USDA in FQPA implementation. We fully support a higher level of USDA participation especially with the planning of mitigation and transition strategies. The department is utilizing the expertise of the land grant universities for further review and input regarding practical solutions. Third, as a result of the TRAC meetings, EPA has decided upon nine science issues that it believes are important for FQPA implementation. Draft positions of the agency on these issues are being published in the Federal Register for public comment over a period of time. We support this type of public participation. Finally, through TRAC, EPA had developed a six phase pilot program for reassessing the tolerances of the OP's. This program involves refining preliminary assessments, review and input by USDA, and risk mitigation discussions involving user groups as well as registrants.

Mr. Chairman, again, allow me to be candid. The recent decisions by the EPA Administrator have literally destroyed any progress that has been made over the last

year through the TRAC process. Any credibility or trust which may have developed regarding a cooperative and consensus building process for implementing FQPA has been demolished.

EPA has decided to target methyl parathion and azinphosmethyl and to cancel and mitigate some of its uses. Fruits and vegetables are going to be most severely impacted. EPA has made these decisions despite the fact that science issues identified in the TRAC discussions and pertinent to these compounds have not been completed. The final determination on the 10X children's safety factor is not expected until March, 2000; yet, EPA is applying a full 10X on methyl parathion and, that is, in spite of new neurotox studies submitted by the registrant. Other pertinent science issues which have not been resolved are the use of human data and the 99.9 percentile. Furthermore, as I said earlier, a six phase pilot process was established for the OP's. In the case of methyl parathion, phases five and six were totally disregarded. EPA has made final decisions on this product and the USDA has not even completed its review. Ms. Browner made a public announcement yesterday even before the technical briefing was convened. The affected users were not consulted as these decisions were being made.

We have already seen what results from the use of more reliable and refined data. The preliminary reassessment of azinphosmethyl showed a dietary risk to infants under one year old that was 10,000 percent of the risk cup. The use of better data brought that risk down close to 100 percent in the refined assessments. This example illustrates that it is absolutely critical that FQPA be implemented with the use of sound science and reliable data.

Mr. Chairman, as I have said, any hopes of cooperation and progress with EPA concerning FQPA implementation have been shattered. The last year's efforts by the TRAC have been wasted. It is apparent that the current Administrator will ignore the entire consensus building process if it suits her political aspirations. The concern of the NCC is, however, in regards to the precedent that will be established. It is critical that FQPA be implemented using sound science and reliable data. As important is the need for a well-defined and publicly understood process. The need for crop protection products is too vital to production agriculture for the whims of politics.

Mr. Chairman, I thank you again for this opportunity to provide comments on these issues. The NCC looks forward to working with you and your subcommittee to prevent such poor decisions from being made in the future.

STATEMENT OF WAYNE CARLSON

Good Afternoon, Mr. Chairman, ladies and gentlemen. My name is Wayne Carlson. I am vice-president of regulatory affairs and field development for Bayer Corporation's Agriculture Division, headquartered in Kansas City, MO. I'm pleased to have the opportunity to address this committee.

Bayer Corporation is one of the manufacturers of azinphos-methyl, an organophosphate insecticide widely used for the control of insects infesting tree crops. It also is used to a lesser degree in cotton and several other crops.

Azinphos-methyl is procedurally the furthest along of the products being evaluated under the step-wise process laid out in the Tolerance Reassessment Action Committee (TRAC) process. I have been asked to come before you today to describe some of our technical and procedural observations and experiences as our product has gone through the FQPA process.

I'd like to group these comments into three areas: first, science and policy issues, second, the complexity of the process, and, third, the critical importance of carefully implementing FQPA according to procedures discussed during the TRAC process.

Relative to science and policy, experience with our product clearly shows how critical science and policy are to the FQPA implementation process and to future availability of pest control products. The importance of science and policy were recognized early by the FQPA Implementation Working Group (IWG), a coalition of 66 commodity, grower and pesticide-related organizations.

In its publication called "The FQPA Roadmap," IWG outlined eight critical science policy areas which needed to be clarified prior to the FQPA-decision-making process moving forward. This list of science-policy issues has grown to nine as a result of further investigation in the TRAC Process. There are now some 20 individual science policy papers generated, detailing issues in these nine areas. Only one of those has been issued as final. Several are only scheduled and won't be issued yet for some time. These science policies represent the foundation of decision-making under FQPA. Without them, decisions are at best interim, which could have a negative effect on some user groups.

There has been much discussion surrounding the use of default or screening level assessments for products being used while these science policy issues are being finalized. This committee saw, during the April hearings, the differences between a dietary risk assessment based upon default assumptions versus a refined risk assessment—a difference of 10,000 of the risk cup versus about 130 percent of the risk cup for the most sensitive sub-population in the FQPA risk assessment.

That 130 percent is influenced by other policy issues still under debate and discussion, even with the refined dietary exposure values. In fact, there are 11 policy documents of the previously mentioned 20, plus the use of human data that will ultimately influence the decisions on products like azinphos methyl. Bayer Corporation has recently submitted two human studies to EPA and CDPA (California). California has reviewed and accepted the results of these studies in its risk assessment process. U.S. EPA still has not, and we are awaiting its policy decision.

The most critical of all of the policy decisions in question is the 99.9 percentile policy. 99.9 is considered by some to be a default or screening level value; by others, it is considered to be a regulatory point. The azinphos-methyl risk assessment involving dietary exposure showing about 130 percent of the risk cup for the most sensitive sub-population becomes about 80 percent at the 99.75 percentile; 35 percent at the 99th percentile; and only about 14 percent of the 95th percentile, the level normally used to establish significance in scientific studies and the level at which FDA regulates food additives. Use of human data could even further reduce these values several fold. In short, it is entirely possible that one of several policy decisions could result in a risk level well below that of the current assessment of 130 percent.

This brings me to my second concern -the complexity involved in the FQPA process. FQPA requires that all available and reliable data be employed in the process. In the case of the azinphos-methyl dietary risk assessment, 52 crops were included, with some 261 specific food forms, each one requiring separate scientific judgements for application of the 133,708 data points and 40 separate processing factors. This just includes dietary exposure from food. We need to keep in mind that FQPA requires food exposures be combined with water exposures and with exposures resulting from applications in the home, in restaurants, et cetera, for chemicals which are approved for such uses, into what is called an aggregate risk assessment for a single chemical. Finally, exposure from that chemical needs to be added to other chemicals, if they are deemed to share a common mechanism of toxicity, into what is called a cumulative risk assessment.

How to conduct a cumulative assessment is very complicated, and as you can imagine, a critical factor in determining the future of families of important pesticides. If it's done too hurriedly or in an overly conservative manner, pesticide availability will suffer needlessly.

In addition to what we've learned relative to the critical aspects of the science policy issues and the complexity involved in the proper exposure and risk assessment, we've learned the importance of adhering to the process of FQPA implementation as outlined in the TRAC.

In their April testimony before this committee, Jim Aidala and Keith Pitts described a 6-phase pilot process, which, among other things, was to "provide for public participation on risk mitigation measures and practical transition strategies."

Azinphos-methyl, the product furthest along in the process, has just completed Phase 5 , a phase in which risk mitigation proposals were to be submitted by the registrant and other interested parties. Phase 6 was to allow EPA and USDA to work together on risk management strategies. Near the end of the Phase 5 period, Bayer Corporation found itself in intense negotiations on risk mitigation issues.

It was very difficult, in a limited amount of time, to contact the many interested grower and user groups to get their full input to be sure that their needs were being considered in the risk benefit assessments required under FIFRA-regulated mitigation proposals. It is critical that the 6th Phase of the process be included—a process of up to 60 days, wherein EPA, along with USDA, work together to develop risk management strategies, to assure that the users' needs are not ignored.

In conclusion, despite the complexities of FQPA, it is still a good law, one which requires us to bring our best science and data to the process of regulating pesticides. It also is really a powerful law, and it must be implemented with responsibility and reason. EPA and USDA have a responsibility to use the best science available and consult with growers and applicators. We favor legislation that furthers this objective. We have a safe, abundant, and economical food supply. We must act carefully to be sure that it is even safer, more abundant, and more economical in the future.

STATEMENT OF PEYTON A. EGGLESTON, M.D.

I would like to thank Congressman Goodlatte and the members of the subcommittee for asking me to address the issue of using pesticides in the home.

I treat children with asthma living in the inner city of Baltimore. In treating them I use medications but also recommend that those who are allergic avoid allergens in their home that cause asthma. In the inner city one of the most important allergens they must avoid is produced by cockroaches and I must recommend that they use pesticides in their home to do this. Most of my research has been devoted to developing better and safer methods to do this.

As background to why I take this approach I would offer the following:

1. Allergic diseases are extremely common, affecting over 40 million Americans and are the most common cause of work loss and school loss in the United States. These diseases include anaphylaxis, allergic rhinitis or hay fever, and asthma. Over 80 percent of children and young adults with asthma are allergic.

2. Allergic diseases are inherited. A person with allergic genes becomes sensitized to substances called allergens that are occur naturally in the environment. In the case of anaphylaxis, the allergens are proteins found in foods such as peanuts or seafood. In the case of hay fever the allergens are carried in the air on plant pollens. In the case of asthma the important allergens include house dust mites, pets, molds and insects such as cockroaches. People without the allergic genes can live around these things and not become sick.

3. Current epidemiologic evidence from the United States and other countries shows that allergy and exposure are the most important risk factor for of asthma- a much stronger risk than air pollution or even passive cigarette smoke. A recent NIH study examined 1528 children with asthma living in US inner cities. Children who were both exposed to cockroach allergens in their home and allergic to cockroaches were 3 times as likely to be hospitalized for asthma and had 40 percent more wheezy days compared to children who were neither allergic nor exposed.

4. Convincing research from England and elsewhere has shown that avoiding allergens such as house dust mite can reduce symptom and medication needs by 40 to 50 percent over the course of a year. I am currently conducting the first experiment to test whether reducing cockroach allergen in the homes of inner city asthmatic children will reduce the severity of their asthma symptoms.

When I recommend to my patients that they use pesticides in their home, I recognize that there may be risks of exposure, both in terms of chronic toxicity and acute asthma attacks from the odors of the pesticide mixes. To reduce the risk, I recommend that the child not be present during the pesticide application. I also recommend pest control companies that apply pesticides in gel form to cracks and crevices, or use integrated pest management to target the application to areas with highest roach populations. I educate families about putting garbage out frequently, storing food in sealed containers and cleaning food debris to help prevent reinfestation. But there is no alternative method of eradicating roaches and unless the source of the allergen is eliminated, I cannot help my patients avoid an important cause of their chronic asthma. In my mind the benefit of controlling chronic severe asthma outweighs the potential risks of pesticide exposure.

Submitted by Hon. Edolphus Towns

May 8, 1997 – Volume 336, Number 19

ORIGINAL ARTICLE

The Role of Cockroach Allergy and Exposure to Cockroach Allergen in Causing Morbidity among Inner-City Children with Asthma

David L. Rosenstreich, Peyton Eggleston, Meyer Kattan, Dean Baker, Raymond G. Slavin, Peter Gergen, Herman Mitchell, Kathleen McNiff-Mortimer, Henry Lynn, Dennis Ownby, Floyd Malveaux, for the National Cooperative Inner-City Asthma Study

Abstract

Background. It has been hypothesized that asthma-related health problems are most severe among children in inner-city areas who are allergic to a specific allergen and also exposed to high levels of that allergen in bedroom dust.

Methods. From November 1992 through October 1993, we recruited 476 children with asthma (age, four to nine years) from eight inner-city areas in the United States. Immediate hypersensitivity to cockroach, house-dust-mite, and cat allergens was measured by skin testing. We then measured major allergens of cockroach (Bla g 1), dust mites (Der p 1 and Der f 1), and cat dander (Fel d 1) in household dust using monoclonal-antibody-based enzyme-linked immunosorbent assays. High levels of exposure were defined according to proposed thresholds for causing disease. Data on morbidity due to asthma were collected at base line and over a one-year period.

Results. Of the children, 36.8 percent were allergic to cockroach allergen, 34.9 percent to dust-mite allergen, and 22.7 percent to cat allergen. Among the children's bedrooms, 50.2 percent had high levels of cockroach allergen in dust, 9.7 percent had high levels of dust-mite allergen, and 12.6 percent had high levels of cat allergen. After we adjusted for sex, score on the Child Behavior Checklist, and family history of asthma, we found that children who were both allergic to cockroach allergen and exposed to high levels of this allergen had 0.37 hospitalization a year, as compared with 0.11 for the other children ($P = 0.001$), and 2.56 unscheduled medical visits for asthma per year, as compared with 1.43 ($P<0.001$). They also had significantly more days of wheezing, missed school days, and nights with lost sleep, and their parents or other care givers were awakened during the night and changed their daytime plans because of the child's asthma significantly more frequently. Similar patterns were not found for the combination of allergy to dust mites or cat dander and high levels of the allergen.

Conclusions. The combination of cockroach allergy and exposure to high levels of this allergen may help explain the frequency of asthma-related health problems in inner-city children. (N Engl J Med 1997;336:1356-63.)

Source Information

From the Division of Allergy and Immunology, Department of Medicine, Albert Einstein College of Medicine, Bronx, N.Y. (D.L.R.); the Division of Pediatric Allergy and Immunology, Johns Hopkins School of Medicine, Baltimore (P.E.); the Department of Pediatrics, Mount Sinai School of Medicine, New York (M.K.); the Center for Occupational

and Environmental Health, University of California, Irvine (D.B.); the Division of Allergy and Immunology, Department of Medicine, St. Louis University School of Medicine, St. Louis (R.G.S.); the National Institute of Allergy and Infectious Diseases, Bethesda, Md. (P.G.); New England Research Institutes, Watertown, Mass. (H.M., K.M.-M., H.L.); the Division of Allergy, Henry Ford Hospital, Detroit (D.O.); and Howard University, Washington, D.C. (F.M.). Address reprint requests to Dr. Rosenstreich at Albert Einstein College of Medicine, 1300 Morris Park Ave., Bronx, NY 10461.

Additional study investigators are listed in the Appendix.

Appendix

In addition to the authors, the following investigators participated in the study: Albert Einstein School of Medicine, Bronx, N.Y. -- E. Crain and L. Baumas; Children's Memorial Hospital, Chicago -- R. Evans III, J. Lavigne, Y.D. Senturia, C.M. Weil, K.K. Christoffel, and H.J. Binns; Cook County Hospital, Chicago -- M. Sullivan, J.H. Mayefsky, and M.F. McDermott; Rainbow Babies and Children's Hospital, Cleveland -- C. Kercsmar, S. Redline, and S. Wade; Henry Ford Hospital and Medical Center, Detroit -- J.A. Anderson, F.E. Leickly, C.L.M. Joseph, and C. Johnson; Mount Sinai School of Medicine, New York -- C. Lamm, M.T. Tin, G. Butts, E. Luder, and D. Baker; Washington University Medical School, St. Louis -- H.J. Wedner and G. Evans; Howard University, Washington, D.C. -- A. Thomas, S. Molock, and M. Richard; National Institute of Allergy and Infectious Diseases, Program Office, Bethesda, Md. -- E. Smartt, K. Weiss, and R. Kaslow; and New England Research Institutes, Data Coordinating Center, Watertown, Mass. -- E. Wright, K.M. Mortimer, and S. Islam.

Bayer

Agriculture Division

Crop Protection Products

Bayer Corporation
8400 Hawthorn Road
P.O. Box 4913
Kansas City, MO 64120-0013
Phone 816 242 2000

August 10, 1999

The Honorable Bob Goodlatte
Chairman, House Subcommittee
Department Operations, Oversight
Nutrition and Forestry
1301 Longworth Building
Washington, D.C. 20515

Dear Mr. Chairman:

It was a great honor to testify before your subcommittee on August 3. The hearing brought out, in public, many significant aspects of the Food Quality Protection Act implementation that concern us. It was also an opportunity to explore the full Tolerance Reassessment Advisory Committee's (TRAC's) six-step process. As I reviewed the testimony and notes of others involved in the hearing, it occurred to me that some additional information might prove useful. I would like to request that you add to the record some additional written responses that I have prepared to more fully address the questions asked in the hearing. It is my understanding that the hearing record remains open for ten days, so that witnesses may supply additional written responses to better clarify issues raised during the hearing. I hope my additions to the record are useful and I thank you again for the opportunity to appear before the subcommittee.

Sincerely,

BAYER CORPORATION
AGRICULTURE DIVISION

Wayne Carlson, Ph.D.
Vice President
Regulatory Affairs & Field Development

Attachment

Additional Comments and Expanded Responses to Questions at the Department Operations, Oversight, Nutrition and Forestry Subcommittee Hearing, August 3, 1999

Submitted by Wayne Carlson, Vice President, Bayer Corporation

For the Hearing Record

---

1. ***Do you think the TRAC process was followed in EPA's decisions that were announced yesterday?***

I think the TRAC process was followed through the fifth step, which just ended for azinphos-methyl, two weeks ago. At that point, we found ourselves in an awkward position with EPA, trying to accomplish the sixth step in a few days. The sixth step is supposed to be a more complete assessment of the possible impacts of proposed mitigation measures, conducted with the full participation of affected growers. Instead, we became aware of the fact that EPA wanted the sixth step completed in time for the August 3 deadline.

2. ***What other products are available as substitutes for Guthion and Methyl Parathion?***

There are a few very targeted pesticides that could be used to control some of the insects. The problem is that each one affects only a limited group of insects. In order to get the broader impact, such as that produced by using azinphos-methyl, one would have to use several targeted pesticides to obtain the same result. The downside, of course, is that you would be increasing the total pesticide load. Also, some alternative products are not as compatible with Integrated Pest Management programs.

3. ***Are you still conducting studies on Guthion that would provide additional data for a more refined risk assessment?***

Yes, we are conducting field studies, processing studies and market basket surveys.

4. ***Is it true that at the 99.8% confidence level, the risk would be measured at 100 rather than at 130? and at the 95% confidence limit, the risk drops to 14?***

Yes. This emphasizes the critical need to have science policy resolved on this issue, particularly as we move into the cumulative risk assessment phase.

5. ***Do you have confidence in the TRAC process to correctly implement and resolve the scientific issues that surround the implementation of FQPA?***

Yes, in fact, we strongly supported the TRAC process which came about, in part, due to congressional concern and the clear directive of the Vice President. The process, as laid out in TRAC, is a good one. It should be followed and the science policy issues should be completed.

6. ***What can we do to help ?***

It would be good if Congress clarified the process to be followed, preferably in legislation, so that the steps outlined in TRAC can be followed to completion and all interested parties have a chance to give input and necessary scientific data can be submitted. Everyone on this subcommittee seems to agree there is no need to rush to judgement unless there is a clear imminent hazard. The scientific data must be collected and/or supplemented. Congress should make it clear that default assumptions should not be used to calculate final risk assessments. At least in our case, Administrator Browner made clear that there is no imminent hazard. This would tend to support the position that EPA should complete the six-step TRAC process on chemicals before making decisions on risk mitigation or tolerances, particularly if there is no imminent hazard. We support HR1592, and believe this legislation addresses our concerns.

7. ***I would like to ask you about the process you were involved in with EPA and the other registrants that led to the current MOA. Did you feel pressured by EPA to negotiate or did you initiate this process to further mitigate risk voluntarily?***

We were contacted by EPA and told that additional risk mitigation measures would have to be employed. We then began a serious dialogue on technical issues and I began to worry about the effect on growers. That is why I contacted a few of them myself, to find out what impact our proposed changes to risk mitigation would have on their uses. In the short time I had to do this, it became apparent that growers depended heavily on our product and that there were, in some cases, no readily available substitutes. In the end, we reached an agreement with the agency that largely met the needs of the growers and satisfied EPA. We obviously did feel the pressure imposed by the August 3 "deadline" and the impression that, had we not been able to reach agreement, the agency would have begun cancellation proceedings.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 12 1999

OFFICE OF CONGRESSIONAL AND
INTERGOVERNMENTAL RELATIONS

The Honorable Bob Goodlatte
Chairman
Subcommittee on Department
Operations, Oversight, Nutrition and Forestry
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Goodlatte:

Thank you for forwarding follow up questions from the April 22, 1999 hearing on EPA's implementation of the Food Quality Protection Act. We are continuing our efforts to respond to these questions, and are providing this interim letter with the responses that have been finalized to date.

We will continue to forward remaining responses as they are finalized by the Agency.

Sincerely,

for Diane E. Thompson
Associate Administrator

EPA's Responses to Follow-up Questions
to the
House of Representatives Committee on Agriculture
Food Quality Protection Act Oversight Hearing, April 22, 1999

I. New FQPA Exposure Assessment

B. *How does EPA propose that a registrant should estimate potential future drinking water exposures for a new pesticide that has not yet been registered?*

In estimating potential exposure through drinking water, whether it be for a use of a new product, new use of an existing product, or an existing use of a registered product, EPA relies primarily on data from laboratory and field-scale testing conducted by the registrant, although EPA may also use data from other agencies such as USDA, as well as information from the scientific literature. In most cases the Agency starts with mathematical models that use data generated from currently required studies of the fate and transport properties of a pesticide along with available runoff and groundwater models to estimate pesticide concentrations in surface water and groundwater. These scientifically peer-reviewed models are employed as a screening technique. The model-based estimates are compared to levels of concern from a human health standpoint. Because the models contain many conservative assumptions, EPA relies on those screening models to identify, with a high degree of confidence, those pesticides that have a very low likelihood of getting into drinking water at levels of concern to human health.

If estimated levels in groundwater and surface water that is or could be used for drinking water appear to exceed levels of concern from a human health standpoint, pesticide companies could also provide data and assessments of the impact of existing drinking water treatment technology on concentrations as well as an assessment of the availability of such treatment across areas of planned use. EPA's approach to addressing drinking water exposure would use groundwater and surface water monitoring data when these are available, reliable and appropriate for this purpose. Finally, for EPA to use these data and assessments, companies would also need to provide EPA an upper bound estimate of the number of people potentially exposed to levels of concern in drinking water.

C. *In the case of a new product, should an accurate exposure assessment for actual drinking water be conducted after the product has been on the market for several years? Wouldn't this give an accurate picture of potential drinking water exposure under actual use conditions and serve as a necessary validation for any assessment?*

In the majority of cases, EPA can grant a full registration for a new product when its screening models show a very low likelihood of water contamination at levels that would adversely affect human health or the environment. For these pesticides, actual water monitoring studies are not required. Conversely, in situations where data on the fate and transport properties of the pesticide, model-based estimates of pesticide concentrations in water, and, the assessment of the effectiveness and availability of treatment technology present a compelling case for the pesticide posing a significant potential to contaminate drinking water at levels of concern to

human health for a significant number of people, the Agency cannot under the law approve registration of a new pesticide until the applicant provided additional information demonstrating its product's safety.

It is possible, however, that some new pesticides fall in between these two scenarios. That is, EPA lacks the information and data to conclude with an appropriate level of certainty that a particular pesticide poses a significant potential to contaminate drinking water at levels of concern to human health in areas where it would be used. In certain of these instances, EPA has granted conditional registrations. It would in most cases require the registrant to monitor sources of drinking water, as well as finished water, as a condition of the registration. Clearly if this monitoring shows that the actual use of the pesticide does not result in significant contamination of drinking water, the Agency would convert the conditional registration to a full registration under section 3 of FIFRA.

D. *For already registered products, what guidance has EPA given the registrants with respect to the types of drinking water exposure data that is sufficient for exposure assessments? Please provide copies of such guidance. What science policies have been developed to address drinking water exposure assessments? What is the status of completion of these drinking water specific science policies?*

EPA's November 17, 1997 policy statement tells registrants how it is factoring drinking water into its tolerance decision making process. Since the passage of FQPA the Agency has also, on a pesticide-specific basis, required the collection of water monitoring data for FQPA risk assessment purposes and has provided individualized guidance to the registrant.

In January of this year, EPA issued for public review and comment a science policy paper on its approaches to estimating pesticide concentrations in drinking water. Additional policy papers on drinking water assessments will be released later this year. More recently, on May 27, the Agency presented to the FIFRA SAP its latest analyses of the impact of making changes to its initial screening models for assessing the impact of pesticide use on drinking water derived from surface water. EPA will consider the comments made by the Panel in deciding whether to move forward to implement these changes to our existing screening models.

In addition to its own efforts, EPA is cooperating with the International Life Sciences Institute (ILSI) on a project initiated by ILSI's Risk Science Institute to evaluate methods that government and industry can use to conduct more reliable assessments of pesticide use on drinking water residues. ILSI has just issued its final report on this topic. The Agency is also in preliminary discussions with the American Crop Protection Association (ACPA) as it works to design a national survey of pesticides in drinking water derived from surface water. We are in the process of evaluating ACPA's proposed protocol.

EPA expects to revise its existing process for factoring drinking water into FQPA decisions over the next several months, as we complete peer review processes on technical matters and make needed decisions.

E. *Will these policies require product specific data submissions? If so, has the Agency notified individual registrants of those requirements? Has EPA validated protocols for such studies?*

Although the Agency has on occasion, on a pesticide-specific basis, required the collection of water monitoring data for FQPA risk assessment purposes, it has not pursued such monitoring on a routine basis. EPA, however, expects to receive significantly more drinking water-related monitoring data in the near term from pesticide registrants as well as from other sources, and will use data call-ins if such information is reasonably required to support the continuation of a tolerance. There is no standard design for a monitoring program because of the many different ways and locations in which pesticides may be used. Thus, for at least some time into the future, EPA will continue to make decisions about the need for and design of a drinking water monitoring study for a specific pesticide on a case-by-case basis.

The Agency is taking a number of steps to develop a consensus on approaches to monitoring pesticide residues in drinking water. As mentioned, EPA is reviewing a report from ILSI and proposed protocols from ACPA. ACPA and EPA both believe that there may be more cost-effective ways of collecting drinking water monitoring data than conducting individual studies on a pesticide-specific basis. Finally, EPA in conjunction with the U.S. Geological Survey just recently began a pilot reservoir monitoring study the purpose of which is, among other things, to better understand how to best design a larger scale protocol for the monitoring of drinking water for pesticides.

F. *With respect to residential exposures to pesticides, what are the primary indoor and outdoor residential exposure scenarios or activities that EPA is concerned about regarding pesticide exposure?*

Because of FQPA's focus on infant's and children's safety, EPA is most concerned about children's exposures to pesticides in their homes, schools, day-care settings and outdoor play areas. In addition to developing Standard Operating Procedure's (SOPs) for estimating infants' and children's exposures to pesticides in these settings, EPA is conducting research, through its Office of Research and Development (ORD), to measure transfer of pesticide residues from residential surfaces to children's bodies. Information acquired from research or from studies submitted in support of registration should help improve the understanding of which exposure scenarios are of most concern.

G. *Has EPA formally requested exposure data from registrants to address each of these residential exposure activities of concern?*

No. In the majority of cases, EPA is able to evaluate the potential for residential exposure to a pesticide using models and existing data. In general, the Agency attempts to make decisions based on available data, whenever possible, as the cost to industry of producing new studies can be very high. When data are needed, EPA considers whether they are best obtained by using its data call-in authority to require individual registrants to produce data on specific pesticides. EPA is working closely with companies, growers, commodity groups, university researchers, the U.S. Department of Agriculture, and Extension personnel in designing and implementing appropriate, cost efficient data collection methods for evaluating residential pesticide exposure. Nonetheless, the authority to call-in needed data has been one of the Agency's most powerful tools, and we will certainly use it if necessary to conduct a sound risk assessment.

H. *Has the Agency published validated procedures for estimating residential exposures for new products not previously used in residential settings?* and

K. *For products already used in residential settings, does EPA have specific required studies to determine residential exposures? If so, have the protocols for such studies been published?*

The Agency is in the process of stepping up its efforts to more routinely collect residential exposure data, and is developing standardized protocols for completing required residential exposure studies. EPA brought its draft guidelines before the FIFRA SAP in 1998, and is currently responding to the comments raised by that Panel. Much of the current, ongoing research by academia, other offices within EPA, and industry will help the Agency refine its testing guidelines. Not surprisingly, the pesticide chemical industry also is committing substantial resources to this issue.

As mentioned above, EPA has developed and made public Standard Operating Procedures for estimating exposure to pesticides resulting from their use in residential and similar sites. These SOPs produce screening level assessments of pesticide exposure and may be performed using information readily available from the pesticide labeling and other generally available data. Thus, they are equally applicable to new products and products that are already in the marketplace. The SOPs represent conservative or screening level estimates of exposure and are used to identify those instances where there may be a potential for concern. If the screening assessments indicate that the risk would be acceptable, no further analysis would be required. In the event, however, that the SOPs estimate potential exposures of concern, the Agency may require additional information, determined on a case-by-case basis, to produce a more realistic estimate. In most cases, reliable data (either modeling or from direct measurement) are available and are used in an assessment.

In addition to any specific required studies, EPA can utilize data from other sources in its residential exposure assessments. In addition to ORD's children's exposure research activities, EPA is also looking into the use of exposure data from turf uses, spray drift studies and farm

worker children analyses. These use scenarios are not directly residential uses of chemicals but may lead to some exposure in the residential environment.

I. *What residential exposure data have been required in the Data Call-In for the Outdoor Residential Task Force? What are the relevant deadlines for submission and review of those data? What is the relevance of this data call-in to FQPA requirements for aggregate exposure assessment? Will the aggregate exposure assessments be conducted for pesticides subject to this data call-in prior to submission and review of the data? How will risk management decisions take into account the results of this data call-in? What is the Agency's obligation to consider outstanding data call-ins in the risk assessment process, and how will this be reconciled with FQPA deadlines for tolerance review?*

EPA called in data to meet four current guideline requirements: Foliar Residue dissipation, Dermal Exposure Upon Reentry, Dermal Exposure to Mixers, Loaders, and Applicators, and Inhalation Exposures to Mixers, Loaders, and Applicators. The 117 pesticides subject to this Data Call-in were divided into 2 groups, based on their toxicity or usage. Data on chemicals in group I (chemicals of greater concern) are due by October 30, 1999. Data on group II (chemicals of less concern) are due by October 29, 2000. EPA will use these data to refine both pathway specific and aggregate exposure assessments for these pesticides. However, because of the Agency's responsibility to take prompt action to mitigate risk, and given the time and expense needed to develop additional data, EPA believes it would not be prudent to delay decisions where available data are sufficient to reach a well reasoned conclusion.

In the interim, for chemicals that the Agency suspects, based on its evaluations, may pose a potential risk concern, it will conduct sensitivity analyses with respect to residential risk when performing its aggregate assessments. For example, if the results of our evaluations indicate a risk level of concern, we would proceed to look at the risk if the exposure duration were half as long, or the amount of residue were less. If the potential risk is alleviated during these analyses, EPA may defer its decision until the pending data are incorporated. If, however, the sensitivity analysis indicates that a potential problem could still exist, we would be confident that even with the more refined data, mitigation measures would still be needed. The Agency is more likely to defer a decision if it believes that the new data will show that existing risk assessments significantly overstate the risk. The Agency is less likely to defer a regulatory decision if it is confident that the new information would have marginal effects on the risk estimates.

J. *Much data have been collected under the auspices of NHEXAS/NHANES that could be used to validate the prevalence of exposures within the general population. Have there been any attempts to validate residential exposure assessments with actual data?*

EPA has used a variety of data to establish the prevalence of pesticide exposures in the general population. For example, a 1995 Centers for Disease Control and Prevention study found a metabolite of a common household insecticide in the urine of 82 percent of the 1000

people monitored. This study was conducted to establish reference concentrations for adults in the general population of the United States. The NHEXAS/NHANES studies will provide useful information when they become available. A 3-day workshop, sponsored by ILSI, is scheduled for October to discuss model evaluation and validation and will include looking at NHEXAS/NHANES data and how it might fit into our modeling scenarios. The data that are being generated under the auspices of NHEXAS and NHANES are likely to provide useful information that will be used in conjunction with other data to address the residential exposure issue.

L. *Have the registrants been notified of product specific data requirements in order to satisfy residential exposure data gaps? Will the data requirement notification process in Sec. 408(f) of FFDCA be utilized as Congress intended? If not, does EPA have an alternate process of data identification and call-in?*

At present, the Agency applies the existing Residential Exposure Assessment SOPs to the development of generic, or chemical-specific, data, and not for the generation of data for individual products (termed product-specific data). The risk assessments are conducted and the tolerances are set based on chemical-specific data.

EPA will use the data requirement notification process in FFDCA section 408(f) when additional data or information are reasonably required to support continuation of a tolerance. The Agency does not believe that section 408(f) requires the deferral of tolerance decision-making until pesticide registrants or others have been given every possible opportunity to generate additional data that may further refine an existing risk assessment. Likewise, the Agency does not interpret section 408(f) as requiring the Agency to "call-in" all data that could conceivably affect a tolerance risk assessment. Where EPA finds that additional data or information are not reasonably required, the Agency will leave it to the discretion of pesticide registrants and other interested parties to determine which additional information they believe would most likely affect risk assessments, and then to submit that information. Many registrants have already chosen to submit additional data, not required by the Agency, to be considered as part of an FQPA tolerance reassessment. (See also our response to question II.M)

M. *What is the process for an interim tolerance reassessment decision while newly required data are being generated by registrants, task forces, etc.?*

If, after careful evaluation of all available information, the Agency still sees a potential significant risk, we believe that it is appropriate to take action to address that risk even though we may still require additional data (or registrants, or others may opt to develop and submit additional data). In cases where new data are essential to a risk determination, EPA may need to employ temporary mitigation measures with the understanding that these measures may be eased or removed if the pending studies show that risks are in fact lower than originally estimated. The concept of maintaining an "interim" tolerance has been suggested by several outside parties, but has not been adopted by the Agency. For example, EPA does issue conditional registrations that

incorporate risk mitigation measures. We are working with USDA, members of the TRAC, and other stakeholders to take a closer look at this and other possibilities to address this issue. The result may be that EPA employs a number of possible strategies. Since each chemical/crop combination is unique, the most appropriate solution may need to be determined on a case-by-case basis.

II. Science Policies

I. *Why has the Agency not written a policy for notice and comment that specifically addresses its interpretation of the "reasonable certainty of no harm" standard?*

The group of science policy issues that are being addressed through the public review process was developed through discussions with stakeholders during the TRAC meetings. The TRAC process did not identify the interpretation of the "reasonable certainty of no harm" standard as a science issue to be raised for public comment.

The "reasonable certainty of no harm" health standard, like its predecessor, the "negligible risk" standard has a long history and is not unfamiliar to those people interested in pesticide regulation. This concept allows the Agency the flexibility to make informed, common-sense decisions--an approach that has widespread acceptance as being the most appropriate for regulatory decisions such as the ones made by EPA. In addition, it should be pointed out that the "reasonable certainty of no harm" standard itself has been used in FFDCA for a long period of time, and it is widely accepted that the standard is both a protective one, and is something short of absolute (*i.e.*, no "bright line").

J. *Does a new data requirement or a requirement to replace a study previously judged acceptable constitute basis for imposing an additional FQPA safety factor, before the registrant has the opportunity to fill that requirement?*

EPA has issued several documents in the past that describe how it interprets this FQPA Safety Factor provision, and it recently completed and sent to the FIFRA SAP a new draft of its interim policy guidance on application of the FQPA Safety Factor. This revised version will be made available for public comment in the near future.

The current draft of EPA's Policy Guidance identifies whether or not to apply an FQPA Safety Factor pending receipt of newly-required studies as one of the more critical issues. Additionally, the interim policy guidance indicates that, in general, EPA will use a weight-of-the-evidence approach to determining the completeness of the database with respect to the toxicity of a pesticide to infants and children. In determining in any particular case whether some safety factor other than the additional default ten-fold factor will be sufficiently protective of infants and children, the Agency will look at all the data it has, as well as the significance of any missing data. The mere fact that some data may be missing does not necessarily mean that the Agency

will not have sufficient, reliable data to determine that a margin of safety, including a factor other than the additional tenfold factor, is safe for infants and children.

K. *How do you weigh benefits and risks of public health pesticide uses under FIFRA when conducting an aggregate risk assessment for that pesticide under the FQPA requirements placed in FFDCA? Have you worked with Health and Human Services in this effort? Who have you worked with? Has a memorandum of understanding been completed between these agencies as required under FQPA?*

FQPA directs the Agency to consider aggregate, non-occupational exposure to a pesticide in determining whether tolerances for that pesticide are safe. The benefits of any use, public health or not, would not be an issue (except in extremely limited circumstances) in determining whether aggregate exposure to the pesticide meets the reasonable certainty of no harm standard in the FFDCA. However, the benefits of public-health uses would be considered by the Agency in determining how best to mitigate any unacceptable risks in order to bring aggregate exposures within safe levels and in determining which tolerances to allow to remain in effect. If the Agency were to determine during this process that a non-food public health use had to be eliminated (for example, in order to allow higher-benefit food uses to remain), the Agency would have to pursue regulatory action under FIFRA, and would be required to consider the benefits of the public health use as part of that action. However, before any regulatory action limiting a public health use of a pesticide can be taken by the Agency, it must consult with the Department of Health and Human Services and USDA on the implication of such an action.

EPA has been working with the Department of Health and Human Services to work out the many details surrounding public health pesticides under FQPA. The Agency has been working with the Office of Public Health and Science, the Center for Food Safety and Applied Nutrition, and the Centers for Disease Control. The two agencies have formed an inter-agency team and are committed to work together to address the issues surrounding public health pesticides and how this group of products can comply with FQPA mandates. The two agencies are in the beginning phases of developing a data development program for public health pesticides. FQPA stipulates that if the regulatory fate of a public health pesticide is in danger because the Agency has insufficient data to support the continued registration, then it is HHS' responsibility to generate the necessary data. It was agreed by all parties that a formal memorandum of understanding was not necessary to attain our common goals.

M. *EPA has recently published for public comment a policy paper titled "Data for refining anticipated residue data estimates used in dietary risk assessments for organophosphate pesticides" (3/26/99) describing various types of bridging data that can be used to refine dietary risk assessments. Does the Agency plan to request any of these studies or other studies arising from any of the nine science policies via a data call-in for use in tolerance reassessments? Is it possible that some of these studies make the difference between keeping and revoking a tolerance for a pesticide? If the study would make such a difference, then would not that information be "reasonably required to support the*

continuation of a tolerance?" In that case would EPA request the data via a data call-in under FFDCA section 408(f)?

To the extent the science papers describe data that could be useful in risk assessments, EPA will address on a case-by-case basis whether such data will be called in. There are cases when some information raises a concern about the potential risks of a particular pesticide, but additional information may show that the concern is less than initially estimated (and could even be judged acceptable). In such circumstances, EPA believes FIFRA and FFDCA give the Agency considerable flexibility in choosing a course of regulatory action that appropriately carries out the broad statutory intent of protecting public health and the environment.

When a risk assessment indicates a potential concern, EPA revisits critical assumptions and pivotal data. It is often at or before this preliminary assessment phase that registrants, growers, or other stakeholders choose to submit additional data relating to their products that assist us in refining the assessment. If, after careful evaluation of all available information, the Agency still sees a significant risk, we believe that it is appropriate to take action to address that risk even though we may still require additional data (or registrants, or others may opt to develop and submit additional data). The Agency recognizes, too, that there may be instances where, after all of the data have been examined, the extent of the risk does not become reasonably clear and the Agency is unable to make a definitive safety finding. Under these circumstances EPA may need to require new studies from the registrant and either defer a decision until the new data are received and reviewed, or make an interim decision.

Finally, it is important to note that neither FIFRA sec. 3(c)(2)(B) nor FFDCA sec. 408(f) forbids EPA from taking regulatory actions for reasons of protecting public health and the environment, pending data submission. Similarly, the Agency does not believe that section 408(f) requires the deferral of decision-making until pesticide registrants or others have been given every possible opportunity to generate additional data that may further refine an existing risk assessment. Indeed, the Committee on Commerce's July 23, 1996 Legislative Report on FQPA (at p. 48) specifically provides that section 408(f) "does not prevent the Administrator from acting to modify or revoke a tolerance or exemption which does not meet the safety standard in subsection (b)(2) or (c)(2)." Just as with FIFRA section 3(c)(2)(B), the Agency believes that it would be inappropriate to state a hard and fast rule for when a regulatory action will be deferred while additional data are being collected and when the Agency will act based on the information it has in hand.

N. *For those science policies that address the new components of tolerance reassessment created by FQPA, do you anticipate that new data will be required? Which science policies do you expect will create new data needs? Will these new data needs require EPA or USDA to create and validate study protocols before registrants or other interested stakeholders can conduct the appropriate studies? How will the Agency notify registrants of any new data requirements? Will the new data needs differ from product to*

product? Are they product specific? Will the data requirement notification process in FFDCA section 408(f) be utilized as Congress intended? If not, why not?

Most of EPA's new science policies will not include recommendations for new data. (At present, only the draft science policy document relating to the FQPA Safety Factor, which was presented at the May meeting of the SAP, indicates that EPA intends to require registrants to conduct new testing.) As discussed in answers to earlier questions, EPA tries to make tolerance reassessment decisions based on available information as much as possible. Some pesticide companies, however, are voluntarily performing new studies which EPA will review as it conducts its risk assessments for tolerance reassessment. When requested by a company, EPA provides assistance on the most appropriate study design to help ensure that the resulting data will be as useful as possible. At this point, however, the Agency does not anticipate that either USDA or it will need to create or validate new study protocols.

EPA expects that new data developed for tolerance reassessment, whether produced voluntarily or in response to Agency data requirements, will usually concern a specific active ingredient, and therefore will be applicable to most or all products containing that active ingredient. Because there are many active ingredients undergoing tolerance reassessment and reregistration, the data being generated may differ considerably from product to product.

As to the data requirement procedures in section 408(f), EPA intends to rely on such procedures when data or information are reasonably required to support continuation of a tolerance.

Q. *Please explain how new products can meet new registration standards and data requirements if these requirements are not fully identified? Does EPA intend to reassess old tolerances and set new tolerances on the basis of different sets of data requirements?*

It is important to note that FQPA does not discriminate between a new pesticide and an existing one. All tolerances must meet the new safety standard of "reasonable certainty of no harm." For new food-use product registrations, this means that the Agency cannot establish a tolerance (and therefore cannot grant a registration) unless, based upon the submitted data, it can make this safety finding. To ensure that all existing tolerances also meet the new standard, Congress put forth the mandate to reassess all established tolerances within a ten year time period. For pesticides that are already registered, this means that the Agency cannot (except under extremely limited circumstances) maintain a tolerance unless, based on available and reliable data, it can make this safety finding. Hence, the Agency does not require different data sets for new or old pesticides.

III. TRAC Meetings

B. *At a TRAC work group meeting in early April, EPA discussed risk assessments for two OP pesticides, mentioning that additional data that were not yet submitted, but could affect the risk assessment. Has EPA asked for or does EPA plan to ask for any of those studies via a data call-in under FFDCA section 408(f)? Might any of those studies make the difference between keeping and losing a crop use? If so, would that information be "reasonably required to support the continuation of a tolerance?"* and

D. *With the risk assessment for azinphos-methyl now showing the dietary risk cup for infants above level full, are there any specific uses or tolerances currently in regulatory jeopardy? Does EPA have reliable data to evaluate the contribution of residues in drinking water to the risk cup for azinphos-methyl? How are you going to get the data? Will risk mitigation decisions be made prior to submission and evaluation of those data?*

The Agency believes that it has sufficient data to support a credible, scientifically-based risk assessment for azinphos methyl. Much of the data that were mentioned at the recent TRAC meeting are not expected to change the risk assessment significantly because the Agency has been able to rely on residue monitoring data from FDA and USDA's PDP in the exposure assessment. In addition, the registrant has just submitted to us two human studies, one addressing dietary exposure and one addressing worker exposure. The Agency's approach to these studies will be based on its policy on the consideration of studies using human test subjects. This policy has been brought before both EPA's Science Advisory Board and the FIFRA SAP and we are currently awaiting their input.

The risk assessment for azinphos showed the food contribution to the dietary risk cup, but did not quantify the contribution of drinking water to the dietary risk. For assessing residues in drinking water the Agency relied on limited monitoring data and on estimates from models. To help refine our assessment, the registrant is initiating both a surface water and ground water monitoring study. The ground water study is centered on analyzing residues in karst terrain soils--areas for which the available, but limited, ground water data indicate a concern. The protocols for these studies have been submitted and are being reviewed.

Even without the contribution of possible residues in water, the dietary risk cup for azinphos methyl is estimated to be overflowing for certain population groups. Azinphos methyl is one of the first chemicals to go through the OP regulatory framework and pilot process developed by TRAC and is now in the last two phases. The Agency recently held a technical briefing and released its revised risk assessment to the public. Interested stakeholders now have 60 days in which to provide mitigation proposals. After the Agency has reviewed these proposals, it will develop its position on the risk mitigation measures that may be necessary to address the risk concerns. While we are currently looking only at the risk cup for azinphos methyl, it is important to keep in mind that, as mentioned above, FQPA calls for the Agency to consider the cumulative risk from all of the OPs. EPA recognizes that it may need to impose

future risk mitigation measures for azinphos methyl and other OPs based on its cumulative risk assessment.

E. *The difference between the preliminary and refined risk assessment for azinphos-methyl is astounding. We'd heard rumors that this pesticide was in serious jeopardy. Now it appears that 99% of the risk you were worried about has disappeared. And you are expecting further refinements to reduce the risk estimates even further. Actually that high level of risk wasn't really there in the first place, was it? Do you expect similar stories on dramatic reduction in risks estimates with other OP insecticides?*

The Agency expects there to be differences between its preliminary risk analyses and its refined analyses. As Agency documents clearly explained, the preliminary risk assessments were based on very conservative assumptions. They have been released to the public with the prominent caveat that the values presented represented the earliest stages of risk determinations. Therefore, it was certainly not unexpected to discover that the preliminary risk assessments often overestimated the actual risk of a chemical.

Whether or not to release these risk assessments in their very early stages was a topic of discussion at the TRAC, and was one of the issues that received the most debate. In the end, the TRAC concluded that openness and transparency were the keystone to making FQPA work and that all stakeholders must be afforded the opportunity to participate in the process. In many cases, the comment process is providing the Agency additional health and environmental effects data, use data, or other relevant information from registrants and other stakeholders which EPA is using to refine the risk assessments. Additional relevant data and information can be submitted earlier and be folded into the preliminary assessments thus resulting in a clearer picture of the risks before public release. Because preliminary assessments are becoming more refined from the outset, we expect that the earlier and refined risk estimates may not be as far apart in the future.

F. *How do EPA and USDA take into account the potential for pesticide resistance development in identifying alternative pesticides during the risk management, mitigation, and transition phases of FQPA-mandated tolerance review?*

The Agency has taken an active role in addressing resistance issues for many years. Based on this experience, we recognize that managing the potential for pest resistance is essential for growers. This is particularly important to growers of minor use crops whose selection of pest control products is often limited to relatively few chemicals. With respect to the reassessment of the organophosphate pesticides, the Agency will solicit the aid of USDA, growers, and others in identifying ways to manage the development of resistance in the field.

During the TRAC discussions, pesticide resistance was identified as one of the criteria that should be considered when making a risk management decision and when imposing risk mitigation. When the Agency has completed a refined risk assessment, if EPA's assessment

indicates that the risks are too high, it will issue a call for suggested mitigation options. Growers of affected commodities will be especially encouraged to reply on all aspects of risk management, including the importance of resistance management. Growers' participation and contribution of information is valuable in acquiring an understanding of the development of pesticide resistance and developing approaches to manage resistance. The potential development of pesticide resistance is one of the factors EPA and USDA will be considering in making plans for a reasonable transition for agriculture away from pesticides whose risks cannot be adequately mitigated by other means.

IV. Budget

A. *How did EPA use the extra $15 million awarded for FQPA implementation?*

Congress appropriated a supplemental $15 million in Fiscal Year 1997 to help the Agency get new FQPA activities up and running. These additional funds have been extremely helpful; they enabled us to hire new staff, upgrade support systems, bring more stakeholders into the process, draft key new science methodologies, and expand outreach efforts, among other activities.

○

ISBN 0-16-059452-9

90000

9 780160 594526

dicates that the risks are too high, it will issue a call fo
affected commodities will be especially encouraged t
anagement, including the importance of resistance ma
ntribution of information is valuable in acquiring an u
sticide resistance and developing approaches to mana
pesticide resistance is one of the factors EPA and US
r a reasonable transition for agriculture away from pes
itigated by other means.

'. Budget

How did EPA use the extra $15 million awarded

Congress appropriated a supplemental $15 milli
gency get new FQPA activities up and running. These
lpful; they enabled us to hire new staff, upgrade supp
e process, draft key new science methodologies, and c
tivities.

ISBN 0-16-059452-9